

# **EXHIBIT 2**

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8 **UNITED STATES DISTRICT COURT**  
9 **SOUTHERN DISTRICT OF CALIFORNIA**

10  
11 **IN RE INCRETIN-BASED**  
12 **THERAPIES PRODUCTS**  
**LIABILITY LITIGATION**

Case No. 13md2452-AJB (MDD)

**MDL 2452**

13 *As to All Related and Member Cases*

Magistrate: Hon. Mitchell D. Dembin  
Judge: Hon. Anthony J. Battaglia

14  
15 PROPOUNDING PARTY: Plaintiffs

16 RESPONDING PARTY: Defendant Amylin Pharmaceuticals, LLC

17 SET Plaintiffs' General Causation Requests to Produce –  
18 Propounded on April 8, 2014

19  
20 **DEFENDANT AMYLIN PHARMACEUTICALS, LLC'S RESPONSES AND**  
21 **OBJECTIONS TO PLAINTIFFS' GENERAL CAUSATION REQUESTS**  
22 **FOR THE PRODUCTION OF DOCUMENTS**  
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1 Pursuant to Rule 34 of the Federal Rules of Civil Procedure, defendant  
2 Amylin Pharmaceuticals, LLC (“Amylin”) hereby responds and objects to  
3 Plaintiffs’ General Causation Requests to Produce propounded on April 8, 2014

4 **PRELIMINARY STATEMENT**

5 All references to “Byetta®” within Amylin’s responses and objections refer  
6 to the twice-daily injectable prescription medication that was first approved by the  
7 Food and Drug Administration (“FDA”) as safe and effective on April 28, 2005.  
8 Except as otherwise stated, Amylin has not undertaken to provide information  
9 about any pharmaceutical product other than Byetta®, so defined, as Plaintiffs’  
10 claims in this litigation, as against Amylin, pertain exclusively to Byetta®.

11 All references to “exenatide” (also known as “exendin-4”) within Amylin’s  
12 responses and objections refer to the 39-amino acid synthetic peptide that was  
13 originally identified in the lizard *Heloderma suspectum* and is the active ingredient  
14 in Byetta®.

15 Amylin has responded and objected to Plaintiffs’ Requests in conformity  
16 with the Court’s orders regarding the permissible scope of discovery in the current  
17 phase. All references to “general causation” within Amylin’s responses and  
18 objections refer to the question of whether Byetta® can cause pancreatic cancer, as  
19 defined in prior orders of the Court. *See* 2/18/2014 Initial Case Management  
20 Scheduling Order Regarding General Causation (Doc. No. 325); 3/25/2014 Order  
21 on Joint Motion for Determination of Disputes Related to the Scope of the Written  
22 Discovery Related to General Causation (Doc. No. 377) (“3/25/2014 Order”). As  
23 stated by the Court in its March 7, 2014 order: “The data end-point or ‘cull point’  
24 has been set at February 28, 2014.” 3/07/2014 Amended Order Following Second  
25 Case Management Conference (“3/07/2014 Order”) (Doc. No. 349) at 1:20-22.

26 Amylin’s responses and objections are based on the information and  
27 documents currently known to Amylin and currently in Amylin’s possession,  
28 custody, or control. Because Amylin has not concluded its investigation or

1 discovery of the facts surrounding each Request for Production, and because  
2 Amylin is continuing to complete general causation discovery under the Court's  
3 orders, Amylin reserves the right to supplement, amend, or correct its responses and  
4 objections as necessary.

5 Amylin has made diligent and reasonable efforts to respond to each and  
6 every Request for Production, to the extent it has not been objected to, as Amylin  
7 understands and interprets the Request. If Plaintiffs subsequently assert an  
8 interpretation of a Request that differs from that of Amylin, Amylin reserves the  
9 right to supplement its objections and responses.

10 Consistent with Federal Rules of Civil Procedure 26 and 34, Amylin has not  
11 undertaken to identify information (a) in the possession, custody or control of  
12 Plaintiffs; (b) publicly available; or (c) equally available and/or as readily  
13 accessible to Plaintiffs as to Amylin.

14 Amylin construes Plaintiffs' Requests not to seek privileged information;  
15 information prepared in anticipation of litigation, constituting attorney work  
16 product, or disclosing mental impressions, conclusions, opinions or legal theories of  
17 any attorney or other representative of Amylin; information containing privileged  
18 attorney-client communications; or information that is otherwise protected from  
19 disclosure under applicable privileges, laws, or rules, including, but not limited to,  
20 the attorney-client privilege, the attorney work product doctrine, the joint defense  
21 and common interest privileges, or similar privileges or protections. Amylin  
22 specifically objects to any purported obligation to search for or produced privileged  
23 information. Any disclosure of such protected or privileged information in  
24 response to any Request is inadvertent and is not intended to be, and shall not  
25 operate as, a waiver of any privileges or protections applicable to that or any other  
26 Request, nor is such inadvertent disclosure or production intended to be, nor shall it  
27 constitute a waiver of the right to object to any use of such response, document, or  
28 information contained therein.

1 Amylin does not in any way adopt Plaintiffs' purported instructions or  
2 definitions of words and phrases contained in Plaintiffs' Requests and reserves the  
3 right to object to them to the extent they are inconsistent with the ordinary and  
4 customary meaning of such words and phrases. Amylin objects to Plaintiffs'  
5 purported definitions to the extent they purport to impose any obligations broader  
6 than, or inconsistent with, applicable discovery rules or common law.

7 Amylin further reserves its rights to withhold information that is confidential,  
8 proprietary or trade secret information, and Amylin asserts that any response or  
9 production pursuant to these Requests will be subject to applicable protective  
10 orders.

11 Amylin further reserves its rights to withhold from disclosure information  
12 that, if disclosed, would unduly and improperly invade the protected privacy rights  
13 of Amylin and/or third-party non-litigants.

14 Except as otherwise stated, Amylin construes each and every Request so as  
15 not to seek information relating to foreign entities or countries outside of the United  
16 States. Such information is irrelevant to the claims and defenses of the parties in  
17 this case and is not reasonably calculated to lead to the discovery of admissible  
18 evidence as the events in this action occurred in the United States. Amylin will  
19 produce its regulatory files for the European Medicines Agency ("EMA"), but only  
20 under the unique and specific facts of this case – namely, that Amylin has noted the  
21 EMA's July 2013 conclusion that Byetta® and other incretin-based therapies do not  
22 cause pancreatic cancer, as well as the February 2014 statement jointly authored by  
23 the EMA and the United States Food and Drug Administration ("FDA") that rejects  
24 the hypothesized associations between pancreatic cancer and Byetta® and other  
25 incretin therapies that underlie Plaintiffs' claims. Amylin continues to maintain  
26 that regulatory filings with foreign agencies are irrelevant to product liability  
27 actions in the United States.

28 Amylin further states that the production of any electronically stored

1 information will be made according to the parties' agreed upon specifications, and  
2 that any instructions or directions calling for a different manner or format of  
3 production will be disregarded. Consistent with the Court's January 9, 2014 Order  
4 on Discovery Dispute Regarding Protocols for Electronically Stored Information  
5 (Doc. # 257), Amylin will disregard any request for a format conversion of  
6 materials contained in the documents already produced by Amylin and Lilly in this  
7 litigation, unless Plaintiffs first meet and confer and advance all conversion costs.

8 Amylin preserves (a) the right to raise in any subsequent proceeding or in the  
9 trial of this or any other action all questions of authenticity, foundation, relevancy,  
10 materiality, privilege, and evidentiary admissibility of any information or document  
11 provided or identified in these responses; (b) the right to object on any ground,  
12 whether or not identified herein, to the use or introduction into evidence of any  
13 information or document in any subsequent proceeding or in the trial of this or any  
14 other action; and (c) the right to object on any ground at any time to additional  
15 discovery.

## 16 **SPECIFIC RESPONSES AND OBJECTIONS**

### 17 **REQUEST NO. 1:**

18 The DOCUMENTS identified in YOUR answers to Plaintiffs' General  
19 Causation Interrogatories to Defendant Amylin Pharmaceuticals, LLC

### 20 **RESPONSE TO REQUEST NO. 1:**

21 Subject to the Preliminary Statement, Amylin incorporates by reference all  
22 objections it has lodged to Plaintiffs' General Causation Interrogatories,  
23 propounded on April 8, 2014. Amylin objects to this Request to the extent it refers  
24 to publicly available information that is equally available to Plaintiffs.

25 Subject to and without waiving the foregoing objections, Amylin responds as  
26 follows: Amylin has produced or will produce the documents referenced in its  
27 Interrogatory responses, subject to Amylin's objections to those Interrogatories.

28

1 **REQUEST NO. 2:**

2 The IND/NDA and any SNDAs for BYETTA in native electronic searchable  
3 format as maintained by YOU.

4 **RESPONSE TO REQUEST NO. 2:**

5 Subject to the Preliminary Statement, Amylin objects to this Request on the  
6 grounds that it is overbroad, unduly burdensome, and duplicative of other document  
7 requests, including to the extent it seeks production in “native electronic searchable  
8 format.” Amylin further objects to this Request’s demand for “native format”  
9 files. Production format will be governed by formatting specifications that the  
10 parties agreed upon. Consistent with the Court’s January 9, 2014 Order on  
11 Discovery Dispute Regarding Protocols for Electronically Stored Information (Doc.  
12 # 257) (“January 9, 2014 Order”), Amylin further objects to this Request to the  
13 extent it calls for a format conversion of materials contained in the documents  
14 already produced by Amylin and Lilly in this litigation, unless Plaintiffs first meet  
15 and confer and advance all conversion costs.

16 Subject to and without waiving the foregoing objections, Amylin responds as  
17 follows: The Byetta® IND/NDA covering the period before December 28, 2009  
18 was produced to Plaintiffs in this litigation on December 21, 2012 (Bates  
19 numbers BY00000001-BY00449028) and is updated in Amylin’s concurrent  
20 production in the format agreed upon by the Parties. As of the date of this  
21 response, Amylin will have produced all of the IND and NDA files regarding  
22 exenatide in accordance with the production specifications set forth in the Parties’  
23 agree-upon Electronically Stored Information (“ESI”) Protocol.

24 Notwithstanding the Parties’ agreed-upon ESI Protocol, and even though  
25 Amylin is under no obligation to do so, Amylin will additionally agree to produce  
26 .SAS data contained in exenatide IND and NDA files in either native .XPT format  
27 (for datasets that do not require redaction) or in Microsoft Excel format (for  
28 datasets that require redaction). Along with the supplemental IND and NDA

1 production that Amylin makes today are all of the .SAS datasets (either in native  
2 .XPT format or in Microsoft Excel format) that are associated with the IND and  
3 NDA submission and correspondence materials contained today's supplemental  
4 production. Although Amylin is under no obligation to reformat information  
5 contained in its December 21, 2012 IND and NDA unless Plaintiffs first agree to  
6 bear the cost of the re-production, Amylin will agree to produce .SAS datasets  
7 associated with the submission and correspondence materials contained in its  
8 December 21, 2012 IND and NDA production in the same format as the .SAS  
9 datasets it is producing today.

10 **REQUEST NO. 3:**

11 All other correspondence, data and other DOCUMENTS that YOU provided  
12 to or received from the FDA related to the safety of BYETTA with respect to  
13 pancreatitis and/or pancreatic cancer, which are not part of the IND/NDA or any  
14 SNDAs for BYETTA.

15 **RESPONSE TO REQUEST NO. 3:**

16 Subject to the Preliminary Statement, Amylin objects to this Request as  
17 irrelevant and not reasonably calculated to lead to the discovery admissible  
18 evidence insofar as it seeks correspondence, data and documents "related to the  
19 safety of BYETTA with respect to pancreatitis." The Court's March 25, 2014 order  
20 limited discovery in this phase to "general causation on the link between the  
21 Defendants' pharmaceuticals and *pancreatic cancer*." 3/25/2014 Order (Doc. No.  
22 377) at 3:6-7 (emphasis added). Amylin will only produce documents related to  
23 pancreatitis as part of its attempt to make a comprehensive production of  
24 information relating to the general causation question concerning pancreatic cancer,  
25 and specifically objects to any obligation to separately search for or produce  
26 information about pancreatitis.

27 Subject to and without waiving the foregoing objections, Amylin responds as  
28 follows: Amylin will conduct a reasonable search for any responsive documents in



1 its possession, custody or control. Amylin will produce nonprivileged documents  
2 found in that search that are responsive to this Request. All such searches and  
3 subsequent productions will be governed by the Federal Rules of Civil Procedure,  
4 applicable orders in this case, and any agreements between Amylin and Plaintiffs.

5 **REQUEST NO. 4:**

6 Corporate organization charts that identify the persons with supervisory  
7 responsibility over scientific research into the safety of BYETTA and those  
8 working at their direction; the persons responsible for determining whether  
9 BYETTA causes and/or is capable of CAUSING pancreatic cancer and those  
10 working at their direction; the persons in charge of compiling and reporting  
11 pancreatitis and/or pancreatic cancer ADVERSE EVENTS for BYETTA and those  
12 working at their direction; and the persons in charge of maintaining the source  
13 DOCUMENTS for pancreatitis and/or pancreatic cancer ADVERSE EVENTS for  
14 BYETTA and those working at their direction.

15 **RESPONSE TO REQUEST NO. 4:**

16 Subject to the Preliminary Statement, Amylin objects to this Request as  
17 vague and ambiguous, including without limitation its terms “persons responsible  
18 for determining whether BYETTA CAUSES and/or is capable of CAUSING  
19 pancreatic cancer.”

20 Subject to and without waiving the foregoing objections, Amylin responds as  
21 follows: Amylin refers Plaintiffs to the organizational charts produced on  
22 December 21, 2012 (AMYLN00000001-AMYLN00000180) and on February 7,  
23 2014 (AMYLN03839770-AMYLN03839776). Amylin will conduct a reasonable  
24 search for any additional responsive documents in its possession, custody or  
25 control. Amylin will produce nonprivileged documents found in that search that are  
26 responsive to this Request. All such searches and subsequent productions will be  
27 governed by the Federal Rules of Civil Procedure, applicable orders in this case,  
28 and any agreements between Amylin and Plaintiffs.

1 **REQUEST NO. 5:**

2 A complete list of all BYETTA preclinical, nonclinical and/or animal studies  
3 performed, completed, designed, planned and/or contemplated, identifying them by  
4 name, number or any other designation YOU use to identify them.

5 **RESPONSE TO REQUEST NO. 5:**

6 Subject to the Preliminary Statement, Amylin objects to this Request on the  
7 grounds that it constitutes an Interrogatory, not a Request for Production, and is  
8 duplicative of Plaintiffs' General Causation Interrogatory No. 2 Amylin refers  
9 Plaintiffs to its response and objections to General Causation Interrogatory No. 2,  
10 which are incorporated by reference as if set forth fully here.

11 **REQUEST NO. 6:**

12 For each BYETTA preclinical, nonclinical and/or animal study performed,  
13 completed, designed, planned and/or contemplated, produce the following:

- 14 a. The protocols; data; researcher and/or laboratory technician notebooks,  
15 notes, logs, bench notes, books, computer files and emails; results;  
16 reports; and pancreatic specimens (e.g. histology slides, tissue  
17 samples, etc.) for that study;
- 18 b. The database(s) where the above information can be located; and
- 19 c. If an independent investigator, contract research organization, or other  
20 third party was involved in the study, produce all documents relating  
21 to the work performed, including but not limited to contracts and  
22 communications between YOU and said independent investigator,  
23 contract research organization, or other third party.

24 **RESPONSE TO REQUEST NO. 6:**

25 Subject to the Preliminary Statement, Amylin objects to this Request as  
26 overbroad, unduly burdensome and oppressive, as the burden of collecting all the  
27 specified materials for "each preclinical, nonclinical, and/or animal study  
28 involving" Byetta® would far outweigh the likely benefit to be achieved.

1 Amylin further objects to the Request as overbroad and not reasonably  
2 calculated to lead to the discovery of admissible evidence to the extent it requests  
3 information about preclinical, nonclinical, and animal studies, such as Chemistry,  
4 Manufacturing and Control (“CMC”) studies, that do not contain data relevant to  
5 general causation. Amylin notes that CMC studies are particularly irrelevant  
6 because no plaintiff in this litigation has alleged injuries arising from the use of  
7 Byetta® that did not meet manufacturing specifications, and because the Protective  
8 Order specifically permits the redaction of “manufacturing methods or processes,  
9 including quality control procedures, and proprietary formulas.” See 6/03/2013  
10 Protective Order (“Protective Order”) (Doc. 32) ¶ 2.e.3. CMC studies are a quality  
11 control procedure related to manufacturing.

12 Amylin further objects to this Request as overbroad and not reasonably  
13 calculated to lead to the discovery of admissible evidence to the extent it requests  
14 information about studies that have been merely “designed, planned and/or  
15 contemplated.” The Court’s March 25, 2014 order provides that “permitted  
16 discovery includes *actual scientific evidence* . . . with regard to the causal link in  
17 dispute in this case.” 3/25/2014 Order at 2:20-23 (emphasis added). By agreement  
18 of the parties, the Court ordered February 28, 2014 as the cut-off date for such  
19 evidence. 3/07/2014 Order at 1:20-22. Documents related to studies that were not  
20 completed by February 28, 2014 are not within the scope of permissible general  
21 causation discovery.

22 Amylin further objects to this Request as vague and ambiguous, including  
23 but not limited to its use of the terms “researcher and/or laboratory technician  
24 notebooks, notes, logs, bench notes, books, computer files and emails; results” and  
25 “planned and/or contemplated.” Amylin further objects to this Request to the  
26 extent it requests the production of physical “databases.” Amylin further objects to  
27 this Request to the extent it requests “contracts and communications” between  
28 Amylin and independent investigators, contract research organizations, and other

1 third parties as such materials are not “actual scientific evidence.” The Court’s  
2 March 25, 2014 order expressly stated that “consulting agreements” and “third  
3 party contracts” would not be discoverable in this phase (3/25/2014 Order at 2:24-  
4 28), and Amylin objects to conducting a search for communications with and  
5 documents relating to third-party researchers.

6 Subject to and without waiving the foregoing objections, Amylin responds as  
7 follows: Protocols, final reports and results from preclinical, nonclinical and  
8 animal studies provided to the FDA are included in the Byetta® IND/NDA that  
9 was produced to Plaintiffs on December 21, 2012 and in Amylin’s concurrent  
10 supplemental production of the Byetta® IND/NDA. Amylin refers Plaintiffs,  
11 without limitation, to the following sections of the previously produced Byetta®  
12 IND/NDA:

- 13 • Section 2.4 of the Byetta® NDA (“Nonclinical Overview”), at  
14 BY0000152092-BY0000152128;
- 15 • Section 2.6 of the Byetta® NDA (“Nonclinical Written or Tabulated  
16 Summaries”), at BY0000152173-BY0000152484;
- 17 • Section 2.7.6 of the Byetta® NDA (“Synopsis of Individual Studies”), at  
18 BY0000152852-BY0000152886, BY0000356143-BY0000356144;
- 19 • The “Integrated Summary of Safety Data” in the Byetta® NDA, at  
20 BY0000290801-BY0000294919, BY0000342847-BY0000343056; and
- 21 • Module 4 of the Byetta® NDA (“Nonclinical Study Reports”), largely at  
22 BY153089-BY170102.

23 Amylin further responds that the table of preclinical, nonclinical and animal  
24 studies attached as Exhibit A includes Bates ranges for study protocols and reports.

25 Amylin further responds that it will conduct a reasonable search for  
26 additional preclinical, nonclinical and animal study protocols, reports and results in  
27 its possession, custody or control. Amylin will produce nonprivileged documents  
28

1 found in that search that are responsive to this Request. All such searches and  
2 subsequent productions will be governed by the Federal Rules of Civil Procedure,  
3 applicable orders in this case, and any agreements between Amylin and Plaintiffs.  
4 Amylin will search for materials related to studies that were not completed by  
5 February 28, 2014 only to the extent such materials are otherwise responsive.  
6 Amylin further responds that it will produce documents relating to work performed  
7 for preclinical, nonclinical and animal studies by independent investigators,  
8 contract research organizations, and other third parties only to the extent such  
9 documents are found in reasonable searches of custodial files for otherwise  
10 responsive documents.

11 Amylin further responds that it is willing to meet and confer with Plaintiffs'  
12 counsel over a protocol that would allow Plaintiffs to identify and inspect  
13 responsive materials in addition to reports, protocols and results for specifically  
14 designated studies that are not otherwise subject to an objection as such materials  
15 are kept in the usual course of business at Plaintiffs' own expense and in a manner  
16 that is coordinated with any inspection conducted by Plaintiffs in the California  
17 state-court JCCP Proceeding.

18 **REQUEST NO. 7:**

19 The standard operating procedures and/or policy and procedures manuals for  
20 BYETTA preclinical, nonclinical and animal studies.

21 **RESOPONSE TO REQUEST NO. 7:**

22 Subject to the Preliminary Statement, Amylin objects to this Request to the  
23 extent it requests "standard operating procedures and/or policy and procedures  
24 manuals" for CMC studies, as CMC studies are unrelated to general causation.  
25 Amylin further objects to the Request as vague and ambiguous, including but not  
26 limited to its term "policy and procedure manuals."

27 Subject to and without waiving the foregoing objections, Amylin responds as  
28 follows: Amylin will conduct a reasonable search for any responsive documents in

1 its possession, custody, or control and will produce nonprivileged documents found  
2 in that search that are responsive to this Request. All such searches and subsequent  
3 productions will be governed by the Federal Rules of Civil Procedure, applicable  
4 orders in this case, and any agreements between Amylin and Plaintiffs.

5 **REQUEST NO. 8:**

6 Every DOCUMENT that addresses the significance of any preclinical,  
7 nonclinical and/or animal study in relation to whether BYETTA CAUSES and/or is  
8 capable of CAUSING pancreatic cancer.

9 **RESPONSE TO REQUEST NO. 8:**

10 Subject to the Preliminary Statement, Amylin objects to this Request as  
11 overbroad and unduly burdensome, to the extent it requests “[e]very  
12 DOCUMENT,” such that the likely benefits production are outweighed by the  
13 burdens of production. Amylin further objects to this request to the extent it seeks  
14 documents outside Amylin’s custody or control and documents that are publicly  
15 and equally available to Plaintiffs. Amylin further objects to this request to the  
16 extent it seeks information protected by the Attorney Work Product or Attorney-  
17 Client Privilege. Amylin further objects to this Request as vague and ambiguous,  
18 including but not limited to its terms “addresses the significance” and “is capable of  
19 CAUSING.”

20 Subject to and without waiving the foregoing objections, Amylin responds as  
21 follows: Amylin refers Plaintiffs to the Byetta® IND/NDA previously produced in  
22 this litigation, specifically those sections cited by Bates number in response to  
23 Request No. 6, and its concurrently produced updated Byetta® IND/NDA.

24 Amylin also refers Plaintiffs to the custodial files previously produced by  
25 Amylin on December 21, 2012, March 8, 2013, and October 4, 2013, and to  
26 Amylin’s forthcoming production of custodial files collected using search terms  
27 agreed upon with Plaintiffs. Following a reasonable search, Amylin will produce  
28 nonprivileged documents found in the custodial files that are responsive to this

1 Request. All such searches and subsequent productions will be governed by the  
2 Federal Rules of Civil Procedure, applicable orders in this case, and any agreements  
3 between Amylin and Plaintiffs.

4 **REQUEST NO. 9:**

5 The memoranda, reports and other similar DOCUMENTS that describe the  
6 nature and intended purpose of any preclinical, nonclinical and/or animal studies  
7 involving BYETTA that are not yet started or completed and, to the extent such  
8 DOCUMENTS exist, the protocols; data; researcher and/or laboratory technician  
9 notebooks, notes, logs, bench notes, books, computer files and emails; results;  
10 reports; and pancreatic specimens (e.g. histology slides, tissue samples, etc.) for  
11 each such preclinical, nonclinical and/or animal study.

12 **RESPONSE TO REQUEST NO. 9:**

13 Subject to the Preliminary Statement, Amylin objects to this Request on the  
14 grounds that it is not reasonably calculated to lead to the discovery of evidence  
15 admissible on the question of general causation because preclinical, nonclinical and  
16 animal studies that have not been started or completed do not include data relevant  
17 to general causation. The Court's March 25, 2014 order provides that "permitted  
18 discovery includes *actual scientific evidence* . . . with regard to the causal link in  
19 dispute in this case." 3/25/2014 Order at 2:20-23 (emphasis added). By agreement  
20 of the parties, the Court ordered February 28, 2014 as the cut-off date for such  
21 evidence. 3/07/2014 Order at 1:20-22. Documents related to studies that were not  
22 completed by February 28, 2014 are not within the scope of permissible general  
23 causation discovery.

24 Amylin further objects to the Request as overbroad and not reasonably  
25 calculated to lead to the discovery of admissible evidence to the extent it requests  
26 information about preclinical, nonclinical, and animal studies, such as CMC  
27 studies, that do not contain data relevant to general causation. Amylin notes that  
28 CMC studies are particularly irrelevant because no plaintiff in this litigation has

1 alleged injuries arising from the use of Byetta® that did not meet manufacturing  
2 specifications, and because the Protective Order specifically permits the redaction  
3 of “manufacturing methods or processes, including quality control procedures, and  
4 proprietary formulas.” See Protective Order ¶ 2.e.3. CMC studies are a quality  
5 control procedure related to manufacturing.

6 Amylin further objects to this Request as vague and ambiguous including but  
7 not limited to its requests for information about the “nature” of studies.

8 Subject to and without waiving the foregoing objections, Amylin responds as  
9 follows: The Byetta® IND/NDA produced to Plaintiffs on December 12, 2012 and  
10 the updated Byetta® IND/NDA concurrently produced include protocols for  
11 preclinical, nonclinical and animal studies that may not be completed. Amylin  
12 refers Plaintiffs, without limitation, to the sections of the previously produced  
13 IND/NDA cited in Amylin’s response to Request No. 6. Amylin further responds  
14 that it will produce materials related to studies that were not completed by February  
15 28, 2014 only to the extent such materials are in its prior productions and/or are  
16 otherwise responsive.

17 **REQUEST NO. 10:**

18 A complete list of all BYETTA human studies performed, completed,  
19 designed, planned and/or contemplated, identifying them by name, number or any  
20 other designation YOU use to identify them.

21 **RESPONSE TO REQUEST NO. 10:**

22 Subject to the Preliminary Statement, Amylin objects to this Request on the  
23 grounds that it constitutes an Interrogatory, not a Request for Production and is  
24 duplicative of Plaintiffs’ General Causation Interrogatory No. 2 Amylin refers  
25 Plaintiffs to its response and objections to General Causation Interrogatory No. 2,  
26 which are incorporated by reference as if set forth fully here.

27 **REQUEST NO. 11:**

28 For each BYETTA human study performed, completed, designed, planned



1 and/or contemplated, produce the following:

- 2 a. The protocols; data; researcher and/or laboratory technician notebooks,  
3 notes, logs, bench notes, books, computer files and emails; results;  
4 reports; and pancreatic specimens (e.g. histology slides, tissue  
5 samples, etc.) for that study;
- 6 b. The database(s) where the above information can be located;
- 7 c. All documentation and/or communication regarding sponsorship of the  
8 study; and
- 9 d. If an independent investigator, contract research organization, or other  
10 third party was involved in the study, produce all documents relating  
11 to the work performed, including but not limited to contracts and  
12 communications between YOU and said independent investigator,  
13 contract research organization, or other third party.

14 **RESPONSE TO REQUEST NO. 11:**

15 Subject to the Preliminary Statement, Amylin objects to this Request as  
16 overbroad, unduly burdensome and oppressive, as the burden of collecting all the  
17 specified materials for “each BYETTA human study performed, completed,  
18 designed, planned and/or contemplated,” would far outweigh the likely benefit to be  
19 achieved.

20 Amylin further objects to this Request as overbroad and not reasonably  
21 calculated to lead to the discovery of admissible evidence to the extent it requests  
22 information about studies that have been merely “designed, planned and/or  
23 contemplated.” The Court’s March 25, 2014 order provides that “permitted  
24 discovery includes *actual scientific evidence* . . . with regard to the causal link in  
25 dispute in this case.” 3/25/2014 Order at 2:20-23 (emphasis added). By agreement  
26 of the parties, the Court ordered February 28, 2014 as the cut-off date for such  
27 evidence. 3/07/2014 Order at 1:20-22. Studies that were not completed by  
28 February 28, 2014 are not within the scope of permissible general causation

1 discovery.

2 Amylin further objects to this Request as vague and ambiguous, including  
3 but not limited to its use of the terms “researcher and/or laboratory technician  
4 notebooks, notes, logs, bench notes, books, computer files and emails; results” and  
5 “planned and/or contemplated.” Amylin further objects to this Request to the  
6 extent it requests the production of physical “databases.” Amylin further objects to  
7 this Request to the extent it requests “contracts and communications” between  
8 Amylin and independent investigators, contract research organizations, and other  
9 third parties as such materials are not “actual scientific evidence.” The Court’s  
10 March 25, 2014 order expressly stated that “consulting agreements” and “third  
11 party contracts” would not be discoverable in this phase (3/25/2014 Order at 2:24-  
12 28) and Amylin objects to conducting a search for communications with and  
13 documents relating to third-party researchers.

14 Subject to and without waiving the foregoing objections, Amylin responds as  
15 follows: Protocols, final reports and results from human studies are included in the  
16 Byetta® IND/NDA that was produced to Plaintiffs on December 21, 2012 and  
17 Amylin’s concurrent production of the updated Byetta® IND/NDA. Amylin refers  
18 Plaintiffs, without limitation, to the following sections of the previously produced  
19 Byetta® IND/NDA:

- 20 • Section 2.5 of the Byetta® NDA (“Clinical Overview”), at BY0000152129-  
21 BY0000152172, BY0000356071-BY0000356091;
- 22 • Section 2.7.2 of the Byetta® NDA (“Summary of Clinical Pharmacology  
23 Studies”), at BY0000152499-BY152651;
- 24 • Section 2.7.4 of the Byetta® NDA (“Summary of Clinical Safety”), at  
25 BY0000152752-BY0000152845, BY0000356110-BY0000356142;
- 26 • Section 2.7.6 of the Byetta® NDA (“Synopsis of Individual Studies”), at  
27 BY0000152852-BY0000152886, BY0000356143-BY0000356144;
- 28 • The “Integrated Summary of Safety Data” in the Byetta® NDA, at

- 1 BY0000290801-BY0000294919, BY0000342847-BY0000343056;
- 2 • Module 5 of the Byetta® NDA (“Clinical Study Reports”);
- 3 • Section 7 (“Clinical Studies”) of the Byetta® Periodic Safety Update Reports
- 4 (PSURs), at BY0000354584-BY0000354586, BY0000361457-
- 5 BY0000361458, BY0000364724-BY0000364725, BY0000368480-
- 6 BY0000368481, BY0000372752-BY0000372754, BY0000378155-
- 7 BY0000378156, BY0000383931-BY0000383932, BY0000387737-
- 8 BY0000387738, BY0000412624-BY0000412625; BY0000435101,
- 9 BY0000437985, BY0000440431, BY0000442478, BY0000444568,
- 10 BY0000446463;
- 11 • Section 9 (“Overall Safety Evaluation”) of the Byetta® Periodic Safety
- 12 Update Reports (PSURs), at BY0000354589-BY0000354609,
- 13 BY0000361465-BY0000361487, BY0000364729-BY0000364752,
- 14 BY0000368483-BY0000368508, BY0000372758-BY0000372822,
- 15 BY0000378160-BY0000378200, BY0000383938-BY0000383988,
- 16 BY0000387744-BY0000387817, BY0000412631-BY0000412665,
- 17 BY0000435107-BY0000435136, BY0000437991-BY0000438016,
- 18 BY0000440437-BY0000440475, BY0000442483-BY0000442513,
- 19 BY0000444573-BY0000444592, BY0000446468-BY0000446486; and
- 20 • The relevant Appendices of the Byetta® Periodic Safety Update Reports
- 21 (PSURs), at BY0000361685-BY0000361687 (PSUR 002, Appendix 5,
- 22 “Summary of Targeted New Safety Clinical Studies”), BY0000364999-
- 23 BY0000365001 (PSUR 003, Appendix 5, “Summary of Clinical Studies
- 24 Planned”), BY0000368524-BY0000368526 (PSUR 004, Appendix 3,
- 25 “Summary of Clinical Studies Planned”), BY0000376023-BY0000376026
- 26 (PSUR 005, Appendix 7, “Summary of Clinical Studies”), BY0000381056-
- 27 BY0000381059 (PSUR 006, Appendix 7, “Summary of Clinical Studies”),
- 28 BY0000386403-BY0000386406 (PSUR 007, Appendix 7, “Summary of

1 Clinical Studies”), BY0000389750-BY0000389755 (PSUR 008, Appendix 6,  
2 “Summary of Newly Analyzed Studies”), BY0000389756-BY0000389760  
3 (PSUR 008, Appendix 7, “Safety Studies Initiated, Ongoing, and Analyzed”),  
4 BY0000414492-BY0000414495 (PSUR 009, Appendix 6, “Safety Studies  
5 Completed, Ongoing, and Planned”), BY0000414496-BY0000414497  
6 (PSUR 009, Appendix 7, Pharmacoepidemiology Studies”), BY0000437014-  
7 BY0000437023 (PSUR 010, Appendix 8, Clinical and  
8 Pharmacoepidemiologic Studies), BY0000439630-BY0000439633 (PSUR  
9 011, Appendix 6, Safety Studies), BY0000441792-BY0000441805 (PSUR  
10 012, Appendix 6, Safety Studies), BY0000443860-BY0000443873 (PSUR  
11 013, Appendix 7, Safety Studies), BY0000445866-BY0000445879 (PSUR  
12 014, Appendix 8, Safety Studies), BY0000448214-BY0000448222 (PSUR  
13 015, Appendix 6, Safety Studies).

14 Amylin further responds that the table of human studies attached as Exhibit B  
15 includes Bates ranges for human study protocols and reports.

16 Amylin further responds that it will conduct a reasonable search for  
17 additional human study protocols, reports and results in its possession, custody or  
18 control. Amylin will produce nonprivileged documents found in that search that are  
19 responsive to this Request. All such searches and subsequent productions will be  
20 governed by the Federal Rules of Civil Procedure, applicable orders in this case,  
21 and any agreements between Amylin and Plaintiffs. Amylin will search for  
22 materials related to studies that were not completed by February 28, 2014 only to  
23 the extent such materials are otherwise responsive. Amylin further responds that it  
24 will produce documents relating to work performed for human studies by  
25 independent investigators, contract research organizations, and other third parties  
26 only to the extent such documents are found in reasonable searches of custodial  
27 files for otherwise responsive documents.

28 If after reviewing the study reports Plaintiffs believe production of specific

1 additional materials regarding specific studies is necessary, Amylin will meet and  
2 confer with Plaintiffs regarding the additional materials Plaintiffs seek.

3 **REQUEST NO. 12:**

4 The standard operating procedures and/or policy and procedures manuals for  
5 BYETTA human studies.

6 **RESPONSE TO REQUEST NO. 12:**

7 Subject to the Preliminary Statement, Amylin objects to this Request as  
8 vague and ambiguous, including but not limited to its term “policy and procedure  
9 manuals.”

10 Subject to and without waiving the foregoing objections, Amylin responds as  
11 follows: Amylin will conduct a reasonable search for responsive documents in its  
12 possession, custody, or control. Amylin will produce nonprivileged documents  
13 found in that search that are responsive to this Request. All such searches and  
14 subsequent productions will be governed by the Federal Rules of Civil Procedure,  
15 applicable orders in this case, and any agreements between Amylin and Plaintiffs.

16 **REQUEST NO. 13:**

17 Every DOCUMENT that records, analyzes or discusses information about  
18 each person YOU are aware of who was a participant in a BYETTA human study  
19 and was diagnosed with pancreatitis and/or pancreatic cancer either while still  
20 participating in the study or after withdrawing or otherwise being removed from the  
21 study.

22 **RESPONSE TO REQUEST NO. 13:**

23 Subject to the Preliminary Statement, Amylin objects to this Request as  
24 overbroad and unduly burdensome to the extent it seeks information about “each  
25 person YOU are aware of who was a participant in a BYETTA human study and  
26 was diagnosed with pancreatitis.” The Court’s March 25, 2014 order limited  
27 discovery in this phase to “general causation on the link between the Defendants’  
28 pharmaceuticals and *pancreatic cancer*.” 3/25/2014 Order (Doc. No. 377) at 3:6-7

1 (emphasis added). Amylin will only produce documents related to pancreatitis as  
2 part of its attempt to make a comprehensive production of information relating to  
3 general causation concerning pancreatic cancer, and specifically objects to any  
4 obligation to separately search for or produce information about pancreatitis.

5 Amylin further objects to the Request to the extent it seeks the production of  
6 information that would compromise the privacy of the patients, health care  
7 providers, reporters, or other persons identified in files or data concerning specific  
8 study subjects.

9 Amylin further objects to this Request as vague and ambiguous, including  
10 but not limited to its term “records, analyzes or discusses information about.”

11 Subject to and without waiving the foregoing objections, Amylin responds as  
12 follows: Information about pancreatic cancer adverse events reported for exenatide  
13 users, including those in clinical trials, can be found in documents previously  
14 produced in this litigation, including without limitation the IND/NDA produced to  
15 Plaintiffs on December 21, 2012 (Bates numbers BY00000001-BY00449028),  
16 which included Periodic Safety Update Reports (“PSURs”) and Periodic Adverse  
17 Drug Experience Reports (“PADERS”); adverse event reports produced on  
18 November 18, 2013 (Bates numbers AMYLN03827490-AMYLN03829802);  
19 MedWatch forms and database reports produced on December 23, 2013 (Bates  
20 numbers AMYLN03829803- AMYLN03838851). Amylin further responds that  
21 information about pancreatic cancer adverse events in Byetta® human study  
22 participants is also included in Amylin’s concurrent production of the updated  
23 IND/NDA. Amylin further responds that it is aware of pancreatic cancer events  
24 being reported on the exenatide arm of the following Human studies: 2993-119  
25 (Subject ID 2993-112-108-010820); *H8OCR-GWDK* (Subject ID H8OCR-GWDK-  
26 063-006303); *H8OEW-GWDM* (Subject ID H8OEW-GWDM-153-015313);  
27 *H8OMC-GWAO* (Subject ID H8OMC-GWAO-404-004154); *H8OMC-GWCK*

1 (Subject ID H8OMC-GWCK-052-005203); 2993LAR-105 (Subject ID 2993LAR-  
2 105-231-023105); and H8OJE-GWBX (Subject ID H8OJE-GWBX-021-002103).

3 Amylin further responds that its concurrent and upcoming productions will  
4 include MedWatch forms and native XML data, as specified in Amylin's response  
5 to Plaintiffs' General Causation Interrogatory No. 19, served today, including  
6 pancreatic cancer adverse event reports from study participants.

7 **REQUEST NO. 14:**

8 Every DOCUMENT that addresses the significance of any human study in  
9 relation to whether BYETTA CAUSES and/or is capable of CAUSING pancreatic  
10 cancer.

11 **RESPONSE TO REQUEST NO. 14:**

12 Subject to the Preliminary Statement, Amylin objects to this Request as  
13 overbroad and unduly burdensome, to the extent it requests "[e]very  
14 DOCUMENT," such that the likely benefits production are outweighed by the  
15 burdens of production. Amylin further objects to this request to the extent it seeks  
16 documents outside Amylin's custody or control and documents that are publicly  
17 and equally available to Plaintiffs. Amylin further objects to this request to the  
18 extent it seeks information protected by the Attorney Work Product or Attorney-  
19 Client Privilege. Amylin further objects to this Request as vague and ambiguous,  
20 including but not limited to its terms "addresses the significance" and "is capable of  
21 CAUSING."

22 Subject to and without waiving the foregoing objections, Amylin responds as  
23 follows: Amylin refers Plaintiffs to the Byetta® IND/NDA previously produced in  
24 this litigation, specifically those sections cited by Bates number in response to  
25 Request No. 11, and its concurrently produced updated Byetta® IND/NDA.

26 Amylin also refers Plaintiffs to the custodial files previously produced by  
27 Amylin on December 21, 2012, March 8, 2013, and October 4, 2013, and to  
28 Amylin's upcoming production of custodial files collected using search terms

1 agreed upon with Plaintiffs. Following a reasonable search, Amylin will produce  
2 nonprivileged documents found in the custodial files that are responsive to this  
3 Request. All such searches and subsequent productions will be governed by the  
4 Federal Rules of Civil Procedure, applicable orders in this case, and any agreements  
5 between Amylin and Plaintiffs.

6 **REQUEST NO. 15:**

7 The memoranda, reports and other similar DOCUMENTS that describe the  
8 nature and intended purpose of any human studies involving BYETTA that are not  
9 yet started or completed and, to the extent such DOCUMENTS exist, the study  
10 protocols; data; researcher and/or laboratory technician notebooks, notes, logs, bench  
11 notes, books, computer files and emails; results; reports; and pancreatic  
12 specimens (e.g. histology slides, tissue samples, etc.) for each such  
13 human study.

14 **RESPONSE TO REQUEST NO. 15:**

15 Subject to the Preliminary Statement, Amylin objects to this Request on the  
16 grounds that it is not reasonably calculated to lead to the discovery of evidence  
17 admissible on the question of general causation because human studies that have  
18 not been started or completed do not include data relevant to general causation.  
19 The Court's March 25, 2014 order provides that "permitted discovery includes  
20 *actual scientific evidence* . . . with regard to the causal link in dispute in this case."  
21 3/25/2014 Order at 2:20-23 (emphasis added). By agreement of the parties, the  
22 Court ordered February 28, 2014 as the cut-off date for such evidence. 3/07/2014  
23 Order at 1:20-22. Documents related to studies that were not completed by  
24 February 28, 2014 are not within the scope of permissible general causation  
25 discovery.

26 Amylin further objects to this Interrogatory as vague and ambiguous  
27 including but not limited to its requests for information about the "nature" of  
28 studies.



1 Subject to and without waiving the foregoing objections, Amylin responds as  
2 follows: The Byetta® IND/NDA produced to Plaintiffs on December 12, 2012 and  
3 the updated Byetta® IND/NDA concurrently produced may include protocols and  
4 other information for human studies that may not be completed. Amylin refers  
5 Plaintiffs, without limitation, to the sections of the previously produced IND/NDA  
6 cited in Amylin's response to Request No. 11. Amylin further responds that it will  
7 produce materials related to studies that were not completed by February 28, 2014  
8 only to the extent such materials are in its prior productions and/or are otherwise  
9 responsive.

10 **REQUEST NO. 16:**

11 A complete list of all BYETTA observational studies (including, without  
12 limitation, claims database studies, cohort studies and other epidemiological  
13 studies) performed, completed, designed, planned and/or contemplated, identifying  
14 them by name, number or any other designation YOU use to identify them.

15 **RESPONSE TO REQUEST NO. 16:**

16 Subject to the Preliminary Statement, Amylin objects to this Request on the  
17 grounds that it constitutes an Interrogatory, not a Request for Production and is  
18 duplicative of Plaintiffs' General Causation Interrogatory No. 2 Amylin refers  
19 Plaintiffs to its response and objections to General Causation Interrogatory No. 2,  
20 which are incorporated by reference as if set forth fully here.

21 **REQUEST NO. 17:**

22 For each BYETTA observational study (including, without limitation, claims  
23 database studies, cohort studies and other epidemiological studies) performed,  
24 completed, designed, planned and/or contemplated, produce the following:

- 25 a. The protocols; data; researcher and/or laboratory technician notebooks,  
26 notes, logs, bench notes, books, computer files and emails; results; and  
27 reports for that study;
- 28 b. The database(s) where the above information can be located; and

1 c. If an independent investigator, contract research organization, or other  
2 third party was involved in the study, produce all documents relating  
3 to the work performed, including but not limited to contracts and  
4 communications between YOU and said independent investigator,  
5 contract research organization, or other third party.

6 **RESPONSE TO REQUEST NO. 17:**

7 Subject to the Preliminary Statement, Amylin objects to this Request as  
8 overbroad, unduly burdensome and oppressive, as the burden of collecting all the  
9 specified materials for “each BYETTA observational study . . . performed,  
10 completed, designed, planned and/or contemplated” would far outweigh the likely  
11 benefit to be achieved. Amylin further objects to the Request as vague and  
12 ambiguous, including but not limited to its use of the terms “observational study,”  
13 “researcher and/or laboratory technician notebooks, notes, logs, bench notes, books,  
14 computer files and emails; results” and “planned and/or contemplated.” Amylin  
15 interprets the term “observational study” to refer to epidemiological studies.

16 Amylin further objects to this Request as overbroad and not reasonably  
17 calculated to lead to the discovery of admissible evidence to the extent it requests  
18 information about studies that have been merely “designed, planned and/or  
19 contemplated.” The Court’s March 25, 2014 order provides that “permitted  
20 discovery includes *actual scientific evidence* . . . with regard to the causal link in  
21 dispute in this case.” 3/25/2014 Order at 2:20-23 (emphasis added). By agreement  
22 of the parties, the Court ordered February 28, 2014 as the cut-off date for such  
23 evidence. 3/07/2014 Order at 1:20-22. Studies that were not completed by  
24 February 28, 2014 are not within the scope of permissible general causation  
25 discovery.

26 Amylin further objects to this Request to the extent it requests the production  
27 of physical “databases.” Amylin further objects to this Request to the extent it  
28 requests “contracts and communications” between Amylin and independent

1 investigators, contract research organizations, and other third parties as such  
2 materials are not “actual scientific evidence.” The Court’s March 25, 2014 order  
3 expressly stated that “consulting agreements” and “third party contracts” would not  
4 be discoverable in this phase (3/25/2014 Order at 2:24-28), and Amylin objects to  
5 conducting a search for communications with and documents relating to third-party  
6 researchers.

7 Subject to and without waiving the foregoing objections, Amylin responds as  
8 follows: Protocols, final reports and results from observational studies are included  
9 in the Byetta® IND/NDA that was produced to Plaintiffs on December 21, 2012,  
10 and Amylin’s concurrent production of the updated Byetta® IND/NDA. Amylin  
11 refers Plaintiffs, without limitation, to the following sections of the previously  
12 produced Byetta® IND/NDA:

- 13 • Section 9 (“Overall Safety Evaluation”) of the Byetta® Periodic Safety  
14 Update Reports (PSURs), at BY0000354589-BY0000354609,  
15 BY0000361465-BY0000361487, BY0000364729-BY0000364752,  
16 BY0000368483-BY0000368508, BY0000372758-BY0000372822,  
17 BY0000378160-BY0000378200, BY0000383938-BY0000383988,  
18 BY0000387744-BY0000387817, BY0000412631-BY0000412665,  
19 BY0000435107-BY0000435136, BY0000437991-BY0000438016,  
20 BY0000440437-BY0000440475, BY0000442483-BY0000442513,  
21 BY0000444573-BY0000444592, BY0000446468-BY0000446486.

22 Amylin further responds that the table of observational studies attached as  
23 Exhibit C includes Bates ranges for observational study protocols and reports.

24 Amylin further responds that it will conduct a reasonable search for  
25 additional observational study protocols, reports and results in its possession,  
26 custody or control. Amylin will produce nonprivileged documents found in that  
27 search that are responsive to this Request. All such searches and subsequent  
28 productions will be governed by the Federal Rules of Civil Procedure, applicable

1 orders in this case, and any agreements between Amylin and Plaintiffs. Amylin will  
2 produce materials related to studies that were not completed by February 28, 2014  
3 only to the extent such materials are in its prior productions and/or are otherwise  
4 responsive. Amylin further responds that it will produce documents relating to  
5 work performed for epidemiological studies by independent investigators, contract  
6 research organizations, and other third parties only to the extent such documents are  
7 found in reasonable searches of custodial files for otherwise responsive documents.

8 **REQUEST NO. 18:**

9 The standard operating procedures and/or policy and procedures manuals for  
10 BYETTA observational studies (including, without limitation, claims database  
11 studies, cohort studies and other epidemiological studies).

12 **RESPONSE TO REQUEST NO. 18:**

13 Subject to the Preliminary Statement, Amylin objects to this Request as  
14 vague and ambiguous, including but not limited to its term “policy and procedure  
15 manuals.”

16 Subject to and without waiving the foregoing objections, Amylin responds as  
17 follows: Amylin will conduct a reasonable search for responsive documents in its  
18 possession, custody, or control. Amylin will produce nonprivileged documents  
19 found in that search that are responsive to this Request. All such searches and  
20 subsequent productions will be governed by the Federal Rules of Civil Procedure,  
21 applicable orders in this case, and any agreements between Amylin and Plaintiffs.

22 **REQUEST NO. 19:**

23 Every DOCUMENT that addresses the significance of any observational  
24 studies (including, without limitation, claims database studies, cohort studies and  
25 other epidemiological studies) in relation to whether BYETTA CAUSES and/or is  
26 capable of CAUSING pancreatic cancer.

27 **RESPONSE TO REQUEST NO. 19:**

28 Subject to the Preliminary Statement, Amylin objects to this Request as

1 overbroad and unduly burdensome, to the extent it requests “[e]very  
2 DOCUMENT,” such that the likely benefits production are outweighed by the  
3 burdens of production. Amylin further objects to this request to the extent it seeks  
4 documents outside Amylin’s custody or control and documents that are publicly  
5 and equally available to Plaintiffs. Amylin further objects to this request to the  
6 extent it seeks information protected by the Attorney Work Product or Attorney-  
7 Client Privilege. Amylin further objects to this Request as vague and ambiguous,  
8 including but not limited to its terms “addresses the significance” and “is capable of  
9 CAUSING.”

10 Subject to and without waiving the foregoing objections, Amylin responds as  
11 follows: Amylin refers Plaintiffs to the Byetta® IND/NDA previously produced in  
12 this litigation, specifically those sections cited by Bates number in response to  
13 Request No. 17, and the concurrently produced Byetta® IND/NDA.

14 Amylin also refers Plaintiffs to the custodial files previously produced by  
15 Amylin on December 21, 2012, March 8, 2013, and October 4, 2013, and to  
16 Amylin’s forthcoming production of custodial files collected using search terms  
17 agreed upon with Plaintiffs for key custodians. Following a reasonable search,  
18 Amylin will produce nonprivileged documents found in the custodial files that are  
19 responsive to this Request. All such searches and subsequent productions will be  
20 governed by the Federal Rules of Civil Procedure, applicable orders in this case,  
21 and any agreements between Amylin and Plaintiffs.

22 **REQUEST NO. 20:**

23 The memoranda, reports and other similar DOCUMENTS that describe the  
24 nature and intended purpose of any observational studies (including, without  
25 limitation, claims database studies, cohort studies and other epidemiological  
26 studies) involving BYETTA that are not yet started or completed and, to the extent  
27 such DOCUMENTS exist, the study protocols; data; researcher and/or laboratory  
28 technician notebooks, notes, logs, bench notes, books, computer files and emails;

1 results; and reports for each such study.

2 **RESPONSE TO REQUEST NO. 20:**

3 Subject to the Preliminary Statement, Amylin objects to this Request on the  
4 grounds that it is not reasonably calculated to lead to the discovery of evidence  
5 admissible on the question of general causation because observational studies that  
6 have not been started or completed do not include data relevant to general  
7 causation. The Court's March 25, 2014 order provides that "permitted discovery  
8 includes *actual scientific evidence* . . . with regard to the causal link in dispute in  
9 this case." 3/25/2014 Order at 2:20-23 (emphasis added). By agreement of the  
10 parties, the Court ordered February 28, 2014 as the cut-off date for such evidence.  
11 3/07/2014 Order at 1:20-22. Documents related to studies that were not completed  
12 by February 28, 2014 are not within the scope of permissible general causation  
13 discovery.

14 Amylin further objects to this Interrogatory as vague and ambiguous  
15 including but not limited to its requests for information about the "nature" of the  
16 studies.

17 Subject to and without waiving the foregoing objections, Amylin responds as  
18 follows: The Byetta® IND/NDA produced to Plaintiffs on December 21, 2012 and  
19 the updated Byetta® IND/NDA included in Amylin's concurrent production may  
20 include protocols and other information for observational studies that may not be  
21 completed. Amylin further responds that it will produce materials related to studies  
22 that were not completed by February 28, 2014 only to the extent such materials are  
23 in its prior productions and/or are otherwise responsive.

24 **REQUEST NO. 21:**

25 The standard operating procedures and/or policy and procedures manuals for  
26 BYETTA studies undertaken to determine, in whole or in part, whether BYETTA  
27 CAUSES and/or is capable of CAUSING pancreatic cancer.

28 **RESPONSE TO REQUEST NO. 21:**

1 Subject to the Preliminary Statement, Amylin objects to this Request as  
2 duplicative of Requests Nos. 7, 12, and 18. Amylin further objects to the Request  
3 as vague and ambiguous, including but not limited to its term “policy and procedure  
4 manuals” and “is capable of CAUSING.”

5 Subject to and without waiving the foregoing objections, Amylin responds as  
6 follows: Amylin collects data about potential toxicity and adverse events, including  
7 events related to pancreatic cancer, in every study related to Byetta® that it  
8 undertakes. The collection of such data is part of the purpose of every Byetta®  
9 study undertaken. Amylin refers Plaintiffs to its responses to Requests Nos. 7, 12,  
10 and 18, which are incorporated as if set forth in full here.

11 **REQUEST NO. 22:**

12 The study protocols; data; researcher and/or laboratory technician notebooks,  
13 notes, logs, bench notes, books, computer files and emails; results; and reports that  
14 were provided to the FDA for each study, test, investigation, evaluation and/or  
15 assessment undertaken by YOU for the purpose of determining, in whole or in part,  
16 whether BYETTA CAUSES and/or is capable of CAUSING pancreatic cancer.

17 **RESPONSE TO REQUEST NO. 22:**

18 Subject to the Preliminary Statement, Amylin objects to this Request as  
19 duplicative of Requests Nos. 6, 11, and 17. Amylin further objects to the Request  
20 as overbroad, unduly burdensome and oppressive as it seeks a quantum and type of  
21 information that would be unduly burdensome to collect, and the likely benefits of  
22 producing such information are outweighed by the burdens associated with  
23 production. Amylin further objects to this Request as vague and ambiguous,  
24 including but not limited to its use of the terms “researcher and/or laboratory  
25 technician notebooks, notes, logs, bench notes, books, computer files and emails;  
26 results” and “is capable of CAUSING.” Amylin further objects to the Request on  
27 the grounds that the relevance of scientific evidence is not determined by whether  
28 or not it was submitted to the FDA.

1 Subject to and without waiving the foregoing objections, Amylin responds as  
2 follows: Amylin collects data about potential toxicity and adverse events, including  
3 events related to pancreatic cancer, in every study related to Byetta® that it  
4 undertakes. The collection of such data is part of the purpose of every Byetta®  
5 study undertaken. Amylin refers Plaintiffs to its responses to Requests Nos. 6, 11,  
6 and 17, which are incorporated as if set forth fully here.

7 **REQUEST NO. 23:**

8 The study protocols; data; researcher and/or laboratory technician notebooks,  
9 notes, logs, bench notes, books, computer files and emails; results; and reports that  
10 were not provided to the FDA for each study, test, investigation, evaluation and/or  
11 assessment undertaken by YOU for the purpose of determining, in whole or in part,  
12 whether BYETTA CAUSES and/or is capable of CAUSING pancreatic cancer.

13 **RESPONSE TO REQUEST NO 23:**

14 Subject to the Preliminary Statement, Amylin objects to this Request as  
15 overbroad, unduly burdensome and oppressive as it seeks a quantum and type of  
16 information that would be unduly burdensome to collect, and the likely benefits of  
17 producing such information are outweighed by the burdens associated with  
18 production. Amylin further objects to the Request as vague and ambiguous,  
19 including but not limited to its use of the terms “researcher and/or laboratory  
20 technician notebooks, notes, logs, bench notes, books, computer files and emails;  
21 results.” Amylin further objects to the Request on the grounds that the relevance of  
22 scientific evidence is not determined by whether or not it was submitted to the  
23 FDA.

24 Subject to and without waiving the foregoing objections, Amylin responds as  
25 follows: Amylin collects data about potential toxicity and adverse events, including  
26 events related to pancreatic cancer, in every study related to Byetta® that it  
27 undertakes. The collection of such data is part of the purpose of every Byetta®  
28 study undertaken. Amylin will conduct a reasonable search for any responsive



1 study protocols, final reports or data in its possession, custody, or control. Amylin  
2 will produce nonprivileged materials found in that search that are responsive to this  
3 Request. All such searches and subsequent productions will be governed by the  
4 Federal Rules of Civil Procedure, applicable orders in this case, and any agreements  
5 between Amylin and Plaintiffs.

6 Amylin further responds that if after reviewing the study reports Plaintiffs  
7 believe production of specific additional materials regarding specific studies is  
8 necessary, Amylin will meet and confer with Plaintiffs regarding the additional  
9 materials Plaintiffs seek.

10 **REQUEST NO. 24:**

11 The study protocols; data; researcher and/or laboratory technician notebooks,  
12 notes, logs, bench notes, books, computer files and emails; results; and reports that  
13 were provided to the EMA for each study, test, investigation, evaluation and/or  
14 assessment undertaken by YOU for the purpose of determining, in whole or in part,  
15 whether BYETTA CAUSES and/or is capable of CAUSING pancreatic cancer.

16 **RESPONSE TO REQUEST NO. 24:**

17 Subject to the Preliminary Statement, Amylin objects to this Request as  
18 duplicative of other requests, overbroad, unduly burdensome and oppressive as it  
19 seeks a quantum and type of information that would be unduly burdensome to  
20 collect, and the likely benefits of producing such information are outweighed by the  
21 burdens associated with production. Amylin further objects to this Request as  
22 vague and ambiguous, including but not limited to its use of the terms “researcher  
23 and/or laboratory technician notebooks, notes, logs, bench notes, books, computer  
24 files and emails; results” and “is capable of CAUSING.” Amylin further objects to  
25 the Request on the grounds that the relevance of scientific evidence is not  
26 determined by whether or not it was submitted to the EMA.

27 Subject to and without waiving the foregoing objections, Amylin responds as  
28 follows: Amylin collects data about potential toxicity and adverse events, including

1 events related to pancreatic cancer, in every study related to Byetta® that it  
2 undertakes. The collection of such data is part of the purpose of every Byetta®  
3 study undertaken. Responsive documents may be found in the EMA files to be  
4 included in Amylin's and Lilly's forthcoming productions. Amylin agrees to  
5 produce the EMA files under the unique and specific facts of this case – namely,  
6 that Amylin has noted the EMA's July 2013 conclusion that Byetta® and other  
7 incretin-based therapies do not cause pancreatic cancer, as well as the February  
8 2014 statement jointly authored by the EMA and the FDA that rejects the  
9 hypothesized associations between pancreatic cancer and Byetta® and other  
10 incretin therapies that underlie Plaintiffs' claims. Amylin continues to maintain  
11 that regulatory filings with foreign agencies are irrelevant to products liability  
12 actions in the United States and generally should not be produced in such litigation.

13 **REQUEST NO. 25:**

14 The study protocols; data; researcher and/or laboratory technician notebooks,  
15 notes, logs, bench notes, books, computer files and emails; results; and reports that  
16 were not provided to the EMA for each study, test, investigation, evaluation and/or  
17 assessment undertaken by YOU for the purpose of determining, in whole or in part,  
18 whether BYETTA CAUSES and/or is capable of CAUSING pancreatic cancer.

19 **RESPONSE TO REQUEST NO. 25**

20 Subject to the Preliminary Statement, Amylin objects to this Request as  
21 overbroad, unduly burdensome and oppressive as it seeks a quantum and type of  
22 information that would be unduly burdensome to collect, and the likely benefits of  
23 producing such information are outweighed by the burdens associated with  
24 production. Amylin further objects to the Request as vague and ambiguous,  
25 including but not limited to its use of the terms “researcher and/or laboratory  
26 technician notebooks, notes, logs, bench notes, books, computer files and emails;  
27 results” and “is capable of CAUSING.” Amylin further objects to the Request on  
28 the grounds that the relevance of scientific evidence is not determined by whether

1 or not it was submitted to the EMA.

2 Subject to and without waiving the foregoing objections, Amylin responds as  
3 follows: Amylin collects data about potential toxicity and adverse events, including  
4 events related to pancreatic cancer, in every study related to Byetta® that it  
5 undertakes. The collection of such data is part of the purpose of every Byetta®  
6 study undertaken. Amylin will conduct a reasonable search for any responsive  
7 study protocols, final reports or data in its possession, custody, or control. Amylin  
8 will produce nonprivileged materials found in that search that are responsive to this  
9 Request. All such searches and subsequent productions will be governed by the  
10 Federal Rules of Civil Procedure, applicable orders in this case, and any agreements  
11 between Amylin and Plaintiffs.

12 Amylin further responds that if after reviewing the study reports Plaintiffs  
13 believe production of specific additional materials regarding specific studies is  
14 necessary, Amylin will meet and confer with Plaintiffs regarding the additional  
15 materials Plaintiffs seek.

16 **REQUEST NO. 26:**

17 Every DOCUMENT that addresses the significance of any study, test,  
18 investigation, evaluation and/or assessment undertaken by YOU for the purpose of  
19 determining, in whole or in part, whether BYETTA CAUSES and/or is capable of  
20 CAUSING pancreatic cancer, in relation to whether BYETTA CAUSES and/or is  
21 capable of CAUSING pancreatic cancer.

22 **RESPONSE TO REQUEST NO. 26:**

23 Subject to the Preliminary Statement, Amylin objects to this Request as  
24 duplicative of Requests Nos. 8, 14 and 19, overbroad and unduly burdensome, to  
25 the extent it requests “[e]very DOCUMENT,” such that the likely benefits  
26 production are outweighed by the burdens of production. Amylin further objects to  
27 this request to the extent it seeks information protected by the Attorney Work  
28 Product or Attorney-Client Privilege. Amylin further objects to this Request as

1 vague and ambiguous, including but not limited to its terms “addresses the  
2 significance” and “is capable of CAUSING.”

3 Subject to and without waiving the foregoing objections, Amylin responds as  
4 follows: Amylin collects data about potential toxicity and adverse events, including  
5 events related to pancreatic cancer, in every study related to Byetta® that it  
6 undertakes. The collection of such data is part of the purpose of every Byetta®  
7 study undertaken. Amylin therefore refers Plaintiffs to its responses to Requests  
8 Nos. 8, 14 and 19, which are incorporated as if set forth fully here.

9 **REQUEST NO. 27:**

10 The memoranda, reports and other similar DOCUMENTS that describe the  
11 nature and intended purpose of any study, test, investigation, evaluation and/or  
12 assessment undertaken by YOU for the purpose of determining, in whole or in part,  
13 whether BYETTA CAUSES and/or is capable of CAUSING pancreatic cancer, that  
14 is not yet started or completed and, to the extent such DOCUMENTS exist, the  
15 study protocols; data; researcher and/or laboratory technician notebooks, notes,  
16 logs, bench notes, books, computer files and emails; results; and reports for each  
17 such study, test, investigation, evaluation and/or assessment.

18 **RESPONSE TO REQUEST NO. 27:**

19 Subject to the Preliminary Statement, Amylin objects to this Request on the  
20 grounds that it is not reasonably calculated to lead to the discovery of evidence  
21 admissible on the question of general causation because studies, tests,  
22 investigations, evaluations and assessments that have not been started or completed  
23 do not include data relevant to general causation. The Court’s March 25, 2014  
24 order provides that “permitted discovery includes *actual scientific evidence* . . .  
25 with regard to the causal link in dispute in this case.” 3/25/2014 Order at 2:20-23  
26 (emphasis added). By agreement of the parties, the Court ordered February 28,  
27 2014 as the cut-off date for such evidence. 3/07/2014 Order at 1:20-22.

28 Documents related to studies that were not completed by February 28, 2014 are not

1 within the scope of permissible general causation discovery.

2 Amylin further objects to this Interrogatory as vague and ambiguous  
3 including but not limited to its requests for information about the “nature” of the  
4 studies and its term “is capable of CAUSING.”

5 Subject to and without waiving the foregoing objections, Amylin responds as  
6 follows: Amylin collects data about potential toxicity and adverse events, including  
7 events related to pancreatic cancer, in every study related to Byetta® that it  
8 undertakes. The collection of such data is part of the purpose of every Byetta®  
9 study undertaken. Amylin refers Plaintiffs to its responses to Requests Nos. 9, 15  
10 and 20, which are incorporated as if set forth fully here.

11 **REQUEST NO. 28:**

12 The standard operating procedures and/or policy and procedures manuals for  
13 all other studies YOU are aware of that bear, in whole or in part, on whether  
14 BYETTA CAUSES and/or is capable of CAUSING pancreatic cancer (whether  
15 such study, test, investigation, evaluation and/or assessment involves BYETTA,  
16 another GLP1 receptor or DPP-4 inhibitor, any other drug, or no drug).

17 **RESPONSE TO REQUEST NO. 28:**

18 Subject to the Preliminary Statement, Amylin objects to this Request on the  
19 grounds that it is premature as the determination of whether a study, test,  
20 investigation, evaluation or assessment “bears on” whether Byetta® causes or “is  
21 CAPABLE of” causing pancreatic cancer calls for expert opinion, which will be  
22 disclosed in accordance with the schedule established by the Court.

23 Amylin further objects that the Request is overbroad, oppressive and unduly  
24 burdensome to the extent it seeks information about drugs other than Byetta® or  
25 exenatide, drugs not manufactured, designed, developed and/or tested by Amylin,  
26 and studies, tests, investigations, evaluations and/or assessments not conducted by  
27 Amylin. Amylin further objects to the Request to the extent it seeks information  
28 not in Amylin’s possession, custody, or control. Amylin further objects to the

1 Request as vague and ambiguous, including but not limited to its term “policy and  
2 procedure manuals” and “is capable of CAUSING.”

3 **REQUEST NO. 29:**

4 Every DOCUMENT that addresses the significance of any other study, test,  
5 investigation, evaluation and/or assessment YOU are aware of that bears, in whole  
6 or in part, on whether BYETTA CAUSES and/or is capable of CAUSING  
7 pancreatic cancer (whether such study, test, investigation, evaluation and/or  
8 assessment involves BYETTA, another GLP-1 receptor or DPP-4 inhibitor, any  
9 other drug, or no drug), in relation to whether BYETTA CAUSES pancreatic  
10 cancer.

11 **RESPONSE TO REQUEST NO. 29:**

12 Subject to the Preliminary Statement, Amylin objects to this Request on the  
13 grounds that it is premature as the determination of whether a study, test,  
14 investigation, evaluation or assessment “bears on” whether Byetta® causes or “is  
15 CAPABLE of” causing pancreatic cancer calls for expert opinion, which will be  
16 disclosed in accordance with the schedule established by the Court.

17 Amylin further objects to the Request as overbroad, unduly burdensome and  
18 oppressive in that the potential benefits of collecting such information are  
19 outweighed by the burdens associated with collection. Amylin further objects that  
20 the Request is overbroad, oppressive and unduly burdensome insofar as it seeks  
21 information about drugs other than Byetta® or exenatide, drugs not manufactured,  
22 designed, developed and/or tested by Amylin, and studies, tests, investigations,  
23 evaluations and/or assessments not conducted by Amylin.

24 Amylin further objects to this Request as vague and ambiguous, including  
25 but not limited to its use of the term “bears, in whole or in part, on whether  
26 BYETTA CAUSES and/or is capable of CAUSING pancreatic cancer.”

27 **REQUEST NO. 30:**

28 The memoranda, reports and other similar DOCUMENTS that describe the

1 nature and intended purpose of any other study, test, investigation, evaluation  
2 and/or assessment YOU are aware of that bears, in whole or in part, on whether  
3 BYETTA CAUSES and/or is capable of CAUSING pancreatic cancer (whether  
4 such study, test, investigation, evaluation and/or assessment involves BYETTA,  
5 another GLP-1 receptor or DPP-4 inhibitor, any other drug, or no drug) that is not  
6 yet started or completed and, to the extent such DOCUMENTS exist, the study  
7 protocols; data; researcher and/or laboratory technician notebooks, notes, logs,  
8 bench notes, books, computer files and emails; results; reports; and pancreatic  
9 specimens (e.g., histology slides, tissue samples, etc.) for each such other study,  
10 test, investigation, evaluation and/or assessment.

11 **RESPONSE TO REQUEST NO. 30:**

12 Subject to the Preliminary Statement, Amylin objects to this Request on the  
13 grounds that it is premature as the determination of whether a study, test,  
14 investigation, evaluation or assessment “bears on” whether Byetta® causes or “is  
15 CAPABLE of” causing pancreatic cancer calls for expert opinion, which will be  
16 disclosed in accordance with the schedule established by the Court.

17 Amylin further objects to the Request as overbroad, unduly burdensome and  
18 oppressive in that the potential benefits of collecting the information specified are  
19 outweighed by the burdens associated with collection. Amylin further objects that  
20 the Request is overbroad, oppressive and unduly burdensome insofar as it seeks  
21 information about drugs other than Byetta® or exenatide, drugs not manufactured,  
22 designed, developed and/or tested by Amylin, and studies, tests, investigations,  
23 evaluations and/or assessments not conducted by Amylin. Amylin further objects  
24 to the Request to the extent it seeks information not within Amylin’s possession,  
25 custody or control.

26 Amylin further objects to this Request on the grounds that it is not reasonably  
27 calculated to lead to the discovery of evidence admissible on the question of general  
28 causation because studies, tests, investigations, evaluations and assessments that

1 have not been started or completed do not include data relevant to general  
2 causation. The Court’s March 25, 2014 order provides that “permitted discovery  
3 includes *actual scientific evidence* . . . with regard to the causal link in dispute in  
4 this case.” 3/25/2014 Order at 2:20-23 (emphasis added). By agreement of the  
5 parties, the Court ordered February 28, 2014 as the cut-off date for such evidence.  
6 3/07/2014 Order at 1:20-22. Documents related to studies, tests, investigations,  
7 evaluations and assessments that were not completed by February 28, 2014 are not  
8 within the scope of permissible general causation discovery.

9 Amylin further objects to this Request as vague and ambiguous, including  
10 but not limited to its use of the term “bears, in whole or in part, on whether  
11 BYETTA CAUSES and/or is capable of CAUSING pancreatic cancer.”

12 **REQUEST NO. 31:**

13 The study protocols; data; researcher and/or laboratory technician notebooks,  
14 notes, logs, bench notes, books, computer files and emails; results; reports; and  
15 pancreatic specimens (e.g., histology slides, tissue samples, etc.) that were provided  
16 to the FDA for any other study, test, investigation, evaluation and/or assessment  
17 YOU are aware of that bears, in whole or in part, on whether BYETTA CAUSES  
18 and/or is capable of CAUSING pancreatic cancer (whether such study, test,  
19 investigation, evaluation and/or assessment involves BYETTA, another GLP-1  
20 receptor or DPP-4 inhibitor, any other drug, or no drug).

21 **RESPONSE TO REQUEST NO. 31:**

22 Subject to the Preliminary Statement, Amylin objects to this Request on the  
23 grounds that it is premature as the determination of whether a study, test,  
24 investigation, evaluation or assessment “bears on” whether Byetta® causes or “is  
25 CAPABLE of” causing pancreatic cancer calls for expert opinion, which will be  
26 disclosed in accordance with the schedule established by the Court.

27 Amylin further objects to the Request as overbroad, unduly burdensome and  
28 oppressive in that it seeks a quantum and type of information that would be unduly



1 burdensome to collect, and that the potential benefits of collecting such information  
2 are outweighed by the burdens associated with collection. Amylin further objects  
3 that the Request is overbroad, oppressive and unduly burdensome insofar as it seeks  
4 information about drugs other than Byetta® or exenatide and drugs not  
5 manufactured, designed, developed and/or tested by Amylin, and studies, tests,  
6 investigations, evaluations and/or assessments not conducted by Amylin. Amylin  
7 further objects to the extent the Request seeks information not in Amylin's  
8 possession, custody, or control.

9 Amylin further objects to this Request on the grounds that it is not reasonably  
10 calculated to lead to the discovery of admissible evidence on the question of general  
11 causation because any distinction between what was, or was not, provided to the  
12 FDA has no effect on the scientific question of whether Byetta® causes pancreatic  
13 cancer.

14 Amylin further objects to this Request as vague and ambiguous, including  
15 but not limited to its use of the terms "researcher and/or laboratory technician  
16 notebooks, notes, logs, bench notes, books, computer files and emails; results" and  
17 "bears, in whole or in part, on whether BYETTA CAUSES and/or is capable of  
18 CAUSING pancreatic cancer."

19 **REQUEST NO. 32:**

20 The study protocols; data; researcher and/or laboratory technician notebooks,  
21 notes, logs, bench notes, books, computer files and emails; results; reports; and  
22 pancreatic specimens (e.g., histology slides, tissue samples, etc.) that were not  
23 provided to the FDA for any other study, test, investigation, evaluation and/or  
24 assessment YOU are aware of that bears, in whole or in part, on whether BYETTA  
25 CAUSES and/or is capable of CAUSING pancreatic cancer (whether such study,  
26 test, investigation, evaluation and/or assessment involves BYETTA, another GLP-1  
27 receptor or DPP-4 inhibitor, any other drug, or no drug.

28 **RESPONSE TO REQUEST NO. 32:**

1 Subject to the Preliminary Statement, Amylin objects to this Request on the  
2 grounds that it is premature as the determination of whether a study, test,  
3 investigation, evaluation or assessment “bears on” whether Byetta® causes or “is  
4 CAPABLE of” causing pancreatic cancer calls for expert opinion, which will be  
5 disclosed in accordance with the schedule established by the Court.

6 Amylin further objects to the Request as overbroad, unduly burdensome and  
7 oppressive in that it seeks a quantum and type of information that would be unduly  
8 burdensome to collect, and that the potential benefits of collecting such information  
9 are outweighed by the burdens associated with collection. Amylin further objects  
10 that the Request is overbroad, oppressive and unduly burdensome insofar as it seeks  
11 information about drugs other than Byetta® or exenatide, drugs not manufactured,  
12 designed, developed and/or tested by Amylin, and studies, tests, investigations,  
13 evaluations and/or assessments not conducted by Amylin. Amylin further objects  
14 to the extent the Request seeks information not in Amylin’s possession, custody, or  
15 control.

16 Amylin further objects to this Request on the grounds that it is not reasonably  
17 calculated to lead to the discovery of admissible evidence on the question of general  
18 causation because any distinction between what was, or was not, provided to the  
19 FDA has no effect on the scientific question of whether Byetta® causes pancreatic  
20 cancer.

21 Amylin further objects to this Request as vague and ambiguous, including  
22 but not limited to its use of the terms “researcher and/or laboratory technician  
23 notebooks, notes, logs, bench notes, books, computer files and emails; results” and  
24 “bears, in whole or in part, on whether BYETTA CAUSES and/or is capable of  
25 CAUSING pancreatic cancer.”

26 **REQUEST NO. 33:**

27 The study protocols; data; researcher and/or laboratory technician notebooks,  
28 notes, logs, bench notes, books, computer files and emails; results; reports; and

1 pancreatic specimens (e.g., histology slides, tissue samples, etc.) that were provided  
2 to the EMA for any other study, test, investigation, evaluation and/or assessment  
3 YOU are aware of that bears, in whole or in part, on whether BYETTA CAUSES  
4 and/or is capable of CAUSING pancreatic cancer (whether such study, test,  
5 investigation, evaluation and/or assessment involves BYETTA, another GLP-1  
6 receptor or DPP-4 inhibitor, any other drug, or no drug).

7 **RESPONSE TO REQUEST NO. 33:**

8 Subject to the Preliminary Statement, Amylin objects to this Request on the  
9 grounds that it is premature as the determination of whether a study, test,  
10 investigation, evaluation or assessment “bears on” whether Byetta® causes or “is  
11 CAPABLE of” causing pancreatic cancer calls for expert opinion, which will be  
12 disclosed in accordance with the schedule established by the Court.

13 Amylin further objects to the Request as overbroad, unduly burdensome and  
14 oppressive in that it seeks a quantum and type of information that would be unduly  
15 burdensome to collect, and that the potential benefits of collecting such information  
16 are outweighed by the burdens associated with collection. Amylin further objects  
17 that the Request is overbroad, oppressive and unduly burdensome insofar as it seeks  
18 information about drugs other than Byetta® or exenatide, drugs not manufactured,  
19 designed, developed and/or tested by Amylin, and studies, tests, investigations,  
20 evaluations and/or assessments not conducted by Amylin. Amylin further objects  
21 to the extent the Request seeks information not in Amylin’s possession, custody, or  
22 control.

23 Amylin further objects to this Request on the grounds that it is not reasonably  
24 calculated to lead to the discovery of admissible evidence on the question of general  
25 causation because any distinction between what was, or was not, provided to the  
26 EMA has no effect on the scientific question of whether Byetta® causes pancreatic  
27 cancer.

28 Amylin further objects to this Request as vague and ambiguous, including

1 but not limited to its use of the terms “researcher and/or laboratory technician  
2 notebooks, notes, logs, bench notes, books, computer files and emails; results” and  
3 “bears, in whole or in part, on whether BYETTA CAUSES and/or is capable of  
4 CAUSING pancreatic cancer.”

5 **REQUEST NO. 34:**

6 The study protocols; data; researcher and/or laboratory technician notebooks,  
7 notes, logs, bench notes, books, computer files and emails; results; reports; and  
8 pancreatic specimens (e.g., histology slides, tissue samples, etc.) that were not  
9 provided to the EMA for any other study, test, investigation, evaluation and/or  
10 assessment YOU are aware of that bears, in whole or in part, on whether BYETTA  
11 CAUSES and/or is capable of CAUSING pancreatic cancer (whether such study,  
12 test, investigation, evaluation and/or assessment involves BYETTA, another GLP-1  
13 receptor or DPP-4 inhibitor, any other drug, or no drug).

14 **RESPONSE TO REQUEST NO. 34:**

15 Subject to the Preliminary Statement, Amylin objects to this Request on the  
16 grounds that it is premature as the determination of whether a study, test,  
17 investigation, evaluation or assessment “bears on” whether Byetta® causes or “is  
18 CAPABLE of” causing pancreatic cancer calls for expert opinion, which will be  
19 disclosed in accordance with the schedule established by the Court.

20 Amylin further objects to the Request as overbroad, unduly burdensome and  
21 oppressive in that it seeks a quantum and type of information that would be unduly  
22 burdensome to collect, and that the potential benefits of collecting such information  
23 are outweighed by the burdens associated with collection. Amylin further objects  
24 that the Request is overbroad, oppressive and unduly burdensome insofar as it seeks  
25 information about drugs other than Byetta® or exenatide, drugs not manufactured,  
26 designed, developed and/or tested by Amylin, and studies, tests, investigations,  
27 evaluations and/or assessments not conducted by Amylin. Amylin further objects  
28

1 to the extent the Request seeks information not in Amylin’s possession, custody, or  
2 control.

3 Amylin further objects to this Request on the grounds that it is irrelevant and  
4 not reasonably calculated to lead to the discovery of admissible evidence on the  
5 question of general causation because any distinction between what was, or was  
6 not, provided to the EMA has no effect on the scientific question of whether  
7 Byetta® causes pancreatic cancer.

8 Amylin further objects to this Request as vague and ambiguous, including  
9 but not limited to its use of the terms “researcher and/or laboratory technician  
10 notebooks, notes, logs, bench notes, books, computer files and emails; results” and  
11 “bears, in whole or in part, on whether BYETTA CAUSES and/or is capable of  
12 CAUSING pancreatic cancer.”

13 **REQUEST NO. 35:**

14 All emails, letters, reports, memoranda and other written communications  
15 YOU have sent to or received from any governmental agency (including, without  
16 limitation, the FDA and EMA) or any other entity or person regarding whether  
17 BYETTA or any other GLP-1 agonist or DPP-4 inhibitor CAUSES and/or is  
18 capable of CAUSING pancreatitis and/or pancreatic cancer.

19 **RESPONSE TO REQUEST NO. 35:**

20 Subject to the Preliminary Statement, Amylin objects to this Request  
21 overbroad, unduly burdensome, and oppressive, including without limitation its  
22 request for information about “[a]ll emails, letters, reports, memoranda and other  
23 written communications” without limitation as to time or purpose. Amylin further  
24 objects to the Request on the grounds that it is irrelevant and not reasonably  
25 calculated to lead to the discovery of evidence admissible on the question of general  
26 causation to the extent that it seeks information other than scientific data, as the  
27 Court’s March 25, 2014 order provides that “permitted discovery includes *actual*  
28 *scientific evidence* . . . with regard to the causal link in dispute in this case,”

1 3/25/2014 Order at 2:20-23 (emphasis added), and to the extent it seeks  
2 communications with regulatory agencies outside the United States, as all relevant  
3 actions in these cases occurred in the United States.

4 Amylin further objects to the Request as overbroad, oppressive and unduly  
5 burdensome to the extent that it seeks information about drugs other than Byetta®  
6 and exenatide in litigation that, as it applies to Amylin, only concerns claims related  
7 to Byetta®.

8 Amylin further objects to the Request as irrelevant and not reasonably  
9 calculated to lead to the discovery of admissible information to the extent it seeks  
10 information about a causal relationship between Byetta® (and other drugs) and  
11 pancreatitis. The Court's March 25, 2014 order limited discovery in this phase to  
12 "general causation on the link between the Defendants' pharmaceuticals and  
13 *pancreatic cancer*." 3/25/2014 Order at 3:6-7 (emphasis added). Amylin will only  
14 produce documents related to pancreatitis as part of its attempt to make a  
15 comprehensive production of information relating to general causation concerning  
16 pancreatic cancer, and specifically objects to any obligation to separately search for  
17 or produce information about pancreatitis.

18 Amylin further objects to the Request as vague and ambiguous, including  
19 without limitation its term "is capable of CAUSING pancreatic cancer."

20 Subject to and without waiving the foregoing objections, Amylin responds as  
21 follows: Amylin's communications with the FDA can be found in the Byetta®  
22 IND/NDA included in Amylin's December 21, 2012 production at Bates numbers  
23 BY00000001-BY00449028. Amylin specifically refers Plaintiffs to  
24 communications with the FDA found at Bates numbers BY00390802-BY00403814  
25 and BY00416353-BY00426172. Additional responsive documents may be found  
26 in the concurrently produced supplemental Byetta® IND/NDA and in the EMA  
27 files to be included in Amylin's and Lilly's forthcoming productions. Amylin  
28 agrees to produce the EMA files under the unique and specific facts of this case –

1 namely, that Amylin has noted the EMA's July 2013 conclusion that Byetta® and  
2 other incretin-based therapies do not cause pancreatic cancer, as well as the  
3 February 2014 statement jointly authored by the EMA and the FDA that rejects the  
4 hypothesized associations between pancreatic cancer and Byetta® and other  
5 incretin therapies that underlie Plaintiffs' claims. Amylin continues to maintain  
6 that regulatory filings with foreign agencies are irrelevant to products liability  
7 actions in the United States and generally should not be produced in such litigation.

8 Amylin also refers Plaintiffs to the custodial files produced to Plaintiffs on  
9 December 21, 2012, March 8, 2013, and October 4, 2013, and to the custodial files  
10 to be included in Amylin's forthcoming productions as negotiated with Plaintiffs.  
11 Following a reasonable search, Amylin will produce nonprivileged documents  
12 found in the custodial files that are responsive to this Request. All such searches  
13 and subsequent productions will be governed by the Federal Rules of Civil  
14 Procedure, applicable orders in this case, and any agreements between Amylin and  
15 Plaintiffs. Attached as Exhibit D is a spreadsheet listing the custodians whose files  
16 have previously been produced, the custodians' job titles, and the Bates numbers  
17 containing each custodian's files. Plaintiffs can locate and identify documents  
18 responsive to this Request within these productions as readily as Amylin can.

19 **REQUEST NO. 36:**

20 If any of YOUR employees, officers, directors, agents, contractors, key  
21 opinion leaders, members of speakers' bureaus, advisory board members, or  
22 scientific advisors corresponded with or supplied information or data to the  
23 European Medicines Agency (EMA) about or in connection with any assessments  
24 of whether BYETTA or any other GLP-1 agonist or DPP-4 inhibitor CAUSES  
25 and/or is capable of CAUSING pancreatic cancer (including, without limitation, as  
26 reflected in the EMA's 2013 "Assessment report for GLP-1 based therapies" and its  
27 2014 "Pancreatic Safety of Incretin-Based Drugs – FDA and EMA Assessment"),  
28 produce the correspondence, information or data provided to the EMA, and any

1 correspondence or other DOCUMENTS YOU received from the EMA in response.

2 **RESPONSE TO REQUEST NO. 36:**

3       Subject to the Preliminary Statement, Amylin objects to this Request as  
4 overbroad, oppressive and unduly burdensome, and as seeking information outside  
5 Amylin's custody and control, insofar as it seeks information about  
6 communications by Amylin's "agents, contractors, key opinion leaders, members of  
7 speakers' bureaus, advisory board members, and scientific advisors" as these  
8 persons are not Amylin employees, officers or directors, and to the extent the  
9 Interrogatory seeks information about communications by any persons not made in  
10 the course of their employment by or affiliation with Amylin.

11       Amylin further objects to the Request as irrelevant and not reasonably  
12 calculated to lead to the discovery of admissible evidence as the relevance or  
13 competence of evidence on general causation is not dependent on the entity to  
14 which it was communicated. To the extent this Request seeks evidence that is  
15 relevant to general causation, it is duplicative of Plaintiffs' other requests that seek  
16 such evidence more directly.

17       Amylin further objects to the Request as overbroad, oppressive and unduly  
18 burdensome to the extent that it seeks information about drugs other than Byetta®  
19 or exenatide in litigation that, as it applies to Amylin, concerns only claims related  
20 to Byetta®. Amylin further objects to the Interrogatory as irrelevant and not  
21 reasonably calculated to lead to the discovery of admissible evidence insofar as it  
22 seeks communications "in connection with any assessments of whether BYETTA  
23 or any other GLP-1 agonist or DPP-4 inhibitor CAUSES and/or is capable of  
24 CAUSING pancreatitis." The Court's March 25, 2014 order limited discovery in  
25 this phase to "general causation on the link between the Defendants'  
26 pharmaceuticals and *pancreatic cancer*." 3/25/2014 Order (Doc. No. 377) at 3:6-7  
27 (emphasis added). Amylin will only produce documents related to pancreatitis as  
28 part of its attempt to make a comprehensive production of information relating to



1 general causation concerning pancreatic cancer, and specifically objects to any  
2 obligation to separately search for or produce information about pancreatitis.  
3 Amylin further objects to the Interrogatory as vague and ambiguous, including but  
4 not limited to its term “is capable of CAUSING.”

5 Subject to and without waiving the foregoing objections, Amylin responds as  
6 follows: Responsive documents may be found in the EMA files to be included in  
7 Amylin’s and Lilly’s forthcoming productions. Amylin agrees to produce EMA  
8 files under the unique and specific facts of this case – namely, that Amylin has  
9 noted the EMA’s July 2013 conclusion that Byetta® and other incretin-based  
10 therapies do not cause pancreatic cancer, as well as the February 2014 statement  
11 jointly authored by the EMA and the FDA that rejects the hypothesized associations  
12 between pancreatic cancer and Byetta® and other incretin therapies that underlie  
13 Plaintiffs’ claims. Amylin continues to maintain that regulatory filings with foreign  
14 agencies are irrelevant to products liability actions in the United States and  
15 generally should not be produced in such litigation.

16 **REQUEST NO. 37:**

17 If any of YOUR employees, officers, directors, agents, contractors, key  
18 opinion leaders, members of speakers’ bureaus, advisory board members, or  
19 scientific advisors corresponded with or supplied information or data to the FDA  
20 about or in connection with any assessments of whether BYETTA or any other  
21 GLP-1 agonist or DPP-4 inhibitor CAUSES and/or is capable of CAUSING  
22 pancreatic cancer (including, without limitation, as reflected in the FDA’s 2014  
23 “Pancreatic Safety of Incretin-Based Drugs – FDA and EMA Assessment”),  
24 produce the correspondence, information or data, and any correspondence or other  
25 DOCUMENTS YOU received from the FDA in response.

26 **RESPONSE TO REQUEST NO. 37:**

27 Subject to the Preliminary Statement, Amylin objects to this Request as  
28 overbroad, oppressive and unduly burdensome, and as seeking information outside

1 Amylin's custody and control, insofar as it seeks information about  
2 communications by Amylin's "agents, contractors, key opinion leaders, members of  
3 speakers' bureaus, advisory board members, and scientific advisors" as these  
4 persons are not Amylin employees, officers or directors, and to the extent the  
5 Request seeks information about communications by any persons not made in the  
6 course of their employment by or affiliation with Amylin.

7 Amylin further objects to the Request as irrelevant and not reasonably  
8 calculated to lead to the discovery of admissible evidence as the relevance or  
9 competence of evidence on general causation is not dependent on the entity to  
10 which it was communicated. To the extent this Request seeks evidence that is  
11 relevant to general causation, it is duplicative of Plaintiffs' other requests that seek  
12 such evidence more directly.

13 Amylin further objects to the Request as vague and ambiguous, including but  
14 not limited to its term "is capable of CAUSING."

15 Subject to and without waiving the foregoing objections, Amylin responds as  
16 follows: Amylin's communications with the FDA can be found in the Byetta®  
17 IND/NDA included in Amylin's December 21, 2012 production, specifically at  
18 Bates numbers BY00390802-BY00403814 and BY00416353-BY00426172, and in  
19 the concurrently produced supplemental Byetta® IND/NDA and FDA  
20 correspondence files.

21 **REQUEST NO. 38:**

22 The standard operating procedures and/or policy and procedures manuals for  
23 the handling of pancreatitis and pancreatic cancer ADVERSE EVENTS and  
24 REPORTABLE EVENTS pertaining to BYETTA.

25 **RESPONSE TO REQUEST NO. 38:**

26 Subject to the Preliminary Statement, Amylin objects to this Request as  
27 overbroad and not reasonably calculated to lead to the discovery of admissible  
28 information because adverse event reports are used in the generation of scientific

1 hypotheses, and cannot establish a causal association between a pharmaceutical or  
2 biologic agent and a condition, and are therefore of little or no value in this  
3 litigation.

4 Amylin further objects to the extent the Request assumes or suggests that  
5 Amylin associated a given Adverse Event Report with Byetta®. Amylin's  
6 responsibility is to record and store Adverse Events Reports that are brought to its  
7 attention by reporters, who are in most instances not Amylin employees, under no  
8 obligation to provide Amylin accurate or complete information, and may lack  
9 sufficient information or qualification to associate an Adverse Event with a  
10 pharmaceutical or biologic agent. Amylin objects to any Request that characterizes  
11 the mandated recording and reporting of Adverse Events Reports as an admission  
12 of causation, association, or any other relationship.

13 Amylin further objects to this Request to the extent it seeks information  
14 protected by the attorney-client privilege, attorney work product doctrine, and/or  
15 joint defense privilege, and confidential proprietary and/or trade secret information.

16 Subject to and without waiving the foregoing objections, Amylin responds as  
17 follows: Amylin refers Plaintiffs to documents previously produced in this  
18 litigation, including without limitation Bristol-Myers Squibb Global  
19 Pharmacovigilance and Epidemiology Standard Operating Procedures produced on  
20 February 7, 2014 (AMYLN03838852-AMYLN03839761); Bristol-Myers Squibb  
21 Global Pharmacovigilance and Epidemiology Training Materials produced on  
22 February 8, 2014 (AMYLN03839777-AMYLN03842921); historical Amylin  
23 pharmacovigilance Standard Operating Procedures produced on February 13, 2014  
24 (AMYLN03842922-AMYLN03843892); Amylin's supplemental historical  
25 standard operating procedures produced on May 2, 2014 (AMYLN03844175-  
26 AMYLN03844331 and AMYLN03845162-AMYLN03845162-  
27 AMYLN03845340); and Amylin's training materials produced on May 2, 2014  
28 (AMYLN03844332-AMYLN03845161).

1 **REQUEST NO. 39:**

2 Produce in electronic format complete copies of all databases used to track,  
3 trend, or record information regarding pancreatitis and pancreatic cancer

4 ADVERSE EVENTS that YOU associated with BYETTA. To the extent that  
5 YOUR databases incorporate the following information for pancreatitis and  
6 pancreatic cancer ADVERSE EVENTS for BYETTA, this request includes:

- 7 a. All DOCUMENTS and information in YOUR possession regarding  
8 each ADVERSE EVENT;
- 9 b. Whether the ADVERSE EVENT was in the form of a MedWatch  
10 Report, communication from a medical provider or consumer, an  
11 ADVERSE EVENT REPORT (“AER”) or some other form;
- 12 c. All attempts YOU made to communicate with anyone to gather further  
13 information regarding each ADVERSE EVENT;
- 14 d. All communications YOU made or received, including the substance  
15 of the communications, the identities of any persons YOU  
16 communicated with internally, and the identities of any persons YOU  
17 communicated with externally regarding each ADVERSE EVENT;
- 18 e. The nature and results of any investigations YOU conducted to  
19 determine the CAUSE of each ADVERSE EVENT, and/or the basis of  
20 any decisions not to investigate;
- 21 f. Any experts and/or consultants whom YOU contacted regarding any  
22 ADVERSE EVENT;
- 23 g. YOUR deliberations and decision-making processes used to determine  
24 whether each ADVERSE EVENT was or was not a REPORTABLE  
25 EVENT;
- 26 h. Any action YOU took as a result of each ADVERSE EVENT;
- 27 i. YOUR analysis and conclusions as to the nature, severity and  
28 frequency of each ADVERSE EVENT;

- 1 j. All ADVERSE EVENT report forms, including supplemental reports  
2 and related information, that were submitted to the FDA for each  
3 ADVERSE EVENT;  
4 k. The current status or final disposition of each ADVERSE EVENT; and  
5 l. Any reporting rates analysis and/or trending analysis done regarding  
6 each ADVERSE EVENT.

7 To the extent that YOUR databases do not incorporate some or all of the  
8 information referenced above in subparts a-l, produce the equivalent information by  
9 reference to the business records in which YOU store it.

10 **RESPONSE TO REQUEST NO. 39:**

11 Subject to the Preliminary Statement, Amylin objects to this Request as not  
12 reasonably calculated to lead to the discovery of admissible evidence, unduly  
13 burdensome, and overbroad, and on the grounds that the likely benefit, if any, of the  
14 discovery is outweighed by the substantial burdens of production. Adverse event  
15 reports are used in the generation of scientific hypotheses, and cannot establish a  
16 causal association between a pharmaceutical or biologic agent and a condition, and  
17 are therefore of little or no value in this litigation.

18 Amylin further objects to this Request as overbroad and not reasonably  
19 calculated to lead to the discovery of admissible information to the extent it seeks  
20 information about pancreatitis adverse events. The Court's March 25, 2014 order  
21 limited discovery in this phase to "general causation on the link between the  
22 Defendants' pharmaceuticals and *pancreatic cancer*." 3/25/2014 Order at 3:6-7  
23 (emphasis added). Amylin will only produce documents related to pancreatitis as  
24 part of its attempt to make a comprehensive production of information relating to  
25 the general causation concerning pancreatic cancer, and specifically objects to any  
26 obligation to separately search for or produce information about pancreatitis cases.

27 Amylin further objects to this Request as overbroad, oppressive and unduly  
28

1 burdensome to the extent that it seeks the wholesale production of data in company  
2 databases. If applied uniformly and without exception, Plaintiffs' prescribed  
3 production and database formats would cause Amylin undue and unjustified burden  
4 and expense. Amylin databases overwhelmingly contain information that is not  
5 relevant to Byetta® or pancreatic cancer and the wholesale production of all data in  
6 such databases is not reasonably calculated to lead to the discovery of relevant  
7 evidence. Further, Plaintiffs' request for the production of a "database," if taken  
8 literally, would require Amylin to produce to Plaintiffs the hardware and software  
9 that make up Amylin's safety databases.

10 Amylin further objects to this Request to the extent it seeks the production of  
11 documents relating to reported events regarding non-plaintiffs because the burden  
12 and expense of production outweighs the likelihood those documents will lead to  
13 relevant evidence.

14 Amylin further objects to the Request to the extent it seeks the production of  
15 information that would compromise the privacy of the patients, health care  
16 providers, reporters, or other persons identified in files or data concerning specific  
17 adverse events. Such information is absolutely protected by federal regulation, and  
18 Amylin is not at liberty to disclose it to Plaintiffs. *See* 21 C.F.R. § 20.63;  
19 Protective Order ¶ 2.e.

20 Amylin further objects to the extent the Request assumes or suggests that  
21 Amylin associated a given Adverse Event Report with Byetta®. Amylin's  
22 responsibility is to record and store Adverse Events Reports that are brought to its  
23 attention by reporters, who are in most instances not Amylin employees, under no  
24 obligation to provide Amylin truthful or complete information, and may lack  
25 sufficient information or qualification to associate an Adverse Event with a  
26 pharmaceutical or biologic agent. Amylin objects to any Request that characterizes  
27 the mandated recording and reporting of Adverse Events Reports as an admission  
28

1 of causation, association, or any other relationship.

2 Amylin further objects to this Request to the extent it seeks information  
3 protected by the attorney-client privilege, attorney work product doctrine, and/or  
4 joint defense privilege, and confidential proprietary and/or trade secret information.

5 Amylin further Objects to this Request to the extent it purports to require the  
6 production of any electronically stored information a different manner or format  
7 than called for in the parties' agreed upon specifications.

8 Subject to and without waiving the foregoing objections, Amylin responds as  
9 follows: Amylin refers Plaintiffs to documents previously produced in this  
10 litigation, including without limitation the Byetta® IND/NDA, including  
11 correspondence with the FDA, Periodic Safety Update Reports ("PSURs") and  
12 Periodic Adverse Drug Experience Reports ("PADERs") (Bates numbers  
13 BY00000001-BY00449028); AERs produced on November 18, 2013 (Bates  
14 numbers AMYLN03827490-AMYLN03829802); MedWatch forms and database  
15 reports produced on December 23, 2013 (Bates numbers AMYLN03829803  
16 through AMYLN03838851); and the custodial files previously produced by Amylin  
17 on December 21, 2012, March 8, 2013, and October 4, 2013. A spreadsheet  
18 identifying the Bates numbers associated with a given custodian in Amylin's prior  
19 productions is attached as Exhibit D.

20 Amylin further responds that it is concurrently producing an updated  
21 IND/NDA in the format agreed to by the Parties and files for custodians as  
22 negotiated with Plaintiffs. Following a reasonable search, Amylin will produce  
23 nonprivileged documents found in the custodial files that are responsive to this  
24 Request. All such searches and subsequent productions will be governed by the  
25 Federal Rules of Civil Procedure, applicable orders in this case, and any agreements  
26 between Amylin and Plaintiffs.

27 Amylin's concurrent and forthcoming productions additionally include  
28 MedWatch forms (redacted as required by federal law) and native XML data

(excluding fields that contain information that is or may be prohibited from disclosure under federal law) relating to exenatide adverse event reports for the following Medical Dictionary for Registered Activities (“MedDRA”) terms:

MedDRA Preferred Terms:

- Adenocarcinoma pancreas;
- Carcinoid tumour of the pancreas;
- Gamma radiation therapy to pancreas;
- Metastases to pancreas;
- Pancreatectomy;
- Pancreatic carcinoma;
- Pancreatic carcinoma metastatic;
- Pancreatic carcinoma non-resectable;
- Pancreatic carcinoma recurrent;
- Pancreatic carcinoma resectable;
- Pancreatic carcinoma stage 0;
- Pancreatic carcinoma stage I;
- Pancreatic carcinoma stage II;
- Pancreatic carcinoma stage III;
- Pancreatic carcinoma stage IV;
- Pancreatic lesion excision;
- Pancreatic mass;
- Pancreatic neoplasm;
- Pancreatic neuroendocrine tumour;
- Pancreatic neuroendocrine tumour metastatic;
- Pancreatic sarcoma;
- Pancreaticoduodenectomy;
- Pancreaticosplenectomy;
- Photon radiation therapy to pancreas;



- Radiotherapy to pancreas;
- Solid pseudopapillary tumour of the pancreas;
- X-ray therapy to pancreas

HLGT = Exocrine Pancreas conditions.

**REQUEST NO. 40:**

The complete file that YOU established and maintain in response to each individual pancreatitis and pancreatic cancer ADVERSE EVENT for BYETTA (commonly known as “source files,” ADVERSE EVENT report files, backup files, or files containing source documentation related to ADVERSE EVENTS). This request seeks the production of all DOCUMENTS and information contained or discussed in the source files for each ADVERSE EVENT, which should contain most or all of the DOCUMENTS and information described in the preceding request in subparts a-l.

**RESPONSE TO REQUEST NO. 40:**

Subject to the Preliminary Statement, Amylin objects to this Request as duplicative of Request No. 39, including subpart 39(a). Amylin refers Plaintiffs to its objections and response to Request No. 39, which are incorporated as if set forth fully here. Amylin further objects to the production of source materials related to individual adverse event reports as cumulative of the MedWatch forms and data Amylin is already producing and unduly burdensome, and on the grounds that whatever likely benefit Plaintiffs might hope to gain from the production of these materials is substantially outweighed by the burden of production.

**REQUEST NO. 41:**

To the extent not already produced in response to the preceding requests, produce all DOCUMENTS for each pancreatitis and pancreatic cancer REPORTABLE EVENT for BYETTA, including the following:

- a. All DOCUMENTS and information in YOUR possession regarding each REPORTABLE EVENT;

- 1 b. Whether the REPORTABLE EVENT was in the form of a MedWatch  
2 Report, communication from a medical provider or consumer, an  
3 ADVERSE EVENT REPORT (“AER”) or some other form;
- 4 c. All attempts YOU made to communicate with anyone to gather further  
5 information regarding each REPORTABLE EVENT;
- 6 d. All communications YOU made or received, including the substance  
7 of the communications, the identities of any persons YOU  
8 communicated with internally, and the identities of any persons YOU  
9 communicated with externally regarding each REPORTABLE  
10 EVENT;
- 11 e. The nature and results of any investigations YOU conducted to  
12 determine the CAUSE of each REPORTABLE EVENT, and/or the  
13 basis of any decisions not to investigate;
- 14 f. Any experts and/or consultants whom YOU contacted regarding any  
15 REPORTABLE EVENT;
- 16 g. YOUR deliberations and decision-making processes used to determine  
17 whether each underlying ADVERSE EVENT was or was not a  
18 REPORTABLE EVENT;
- 19 h. Any action YOU took as a result of each REPORTABLE EVENT;
- 20 i. YOUR analysis and conclusions as to the nature, severity and  
21 frequency of each REPORTABLE EVENT;
- 22 j. All REPORTABLE EVENT report forms, including supplemental  
23 reports and related information, that were submitted to the FDA for  
24 each REPORTABLE EVENT;
- 25 k. The current status or final disposition of each REPORTABLE  
26 EVENT; and
- 27 l. Any reporting rates analysis and/or trending analysis done regarding  
28 each REPORTABLE EVENT.

1 **RESPONSE TO REQUEST NO. 41:**

2 Subject to the Preliminary Statement, Amylin objects to this Request as  
3 duplicative of Requests Nos. 39 and 40. Amylin refers Plaintiffs to its objections  
4 and response to Request No. 39 and 40, which are incorporated as if set forth fully  
5 here.

6 **REQUEST NO. 42:**

7 All DOCUMENTS that state or discuss any request by the FDA that YOU  
8 conduct post-market surveillance of BYETTA with respect to pancreatitis and  
9 pancreatic cancer. Include in your response any correspondence, plans, reports, or  
10 other DOCUMENTS submitted by YOU to the FDA in response.

11 **RESPONSE TO REQUEST NO. 42:**

12 Subject to the Preliminary Statement, Amylin objects to this Request as  
13 duplicative of Requests Nos. 2, 3, 39, 40, and 41. Amylin further objects to this  
14 Request as overbroad and not reasonably calculated to lead to the discovery of  
15 admissible information to the extent it seeks information about post-market  
16 surveillance with respect to pancreatitis. The Court's March 25, 2014 order limited  
17 discovery in this phase to "general causation on the link between the Defendants'  
18 pharmaceuticals and *pancreatic cancer*." 3/25/2014 Order at 3:6-7 (emphasis  
19 added). Amylin will only produce documents related to pancreatitis as part of its  
20 attempt to make a comprehensive production of information relating to general  
21 causation concerning pancreatic cancer, and specifically objects to any obligation to  
22 separately search for or produce information about pancreatitis.

23 Amylin further objects to the Request as irrelevant and not reasonably  
24 calculated to lead to the discovery of admissible evidence to the extent it seeks  
25 information other than scientific data regarding general causation. The Court's  
26 March 25, 2014 order provides that "permitted discovery includes *actual scientific*  
27 *evidence* . . . with regard to the causal link in dispute in this case." 3/25/2014 Order  
28 at 2:20-23 (emphasis added).

1 Subject to and without waiving the foregoing objections, Amylin responds as  
2 follows: Amylin refers Plaintiffs to the documents previously produced in this  
3 litigation, including without limitation the Byetta® IND/NDA produced on  
4 December 12, 2012 (Bates numbers BY00000001-BY00449028), which includes  
5 PSURs, and the concurrently produced updated Byetta® IND/NDA. Amylin  
6 further responds that it will conduct a reasonable search for any additional  
7 responsive documents in its possession, custody or control. Amylin will produce  
8 nonprivileged documents found in that search that are responsive to this Request.  
9 All such searches and subsequent productions will be governed by the Federal  
10 Rules of Civil Procedure, applicable orders in this case, and any agreements  
11 between Amylin and Plaintiffs.

12 **REQUEST NO. 43:**

13 All charts, graphs, schematics, reports, memoranda and other similar  
14 DOCUMENTS analyzing, summarizing and/or reporting on pancreatitis and/or  
15 pancreatic cancer ADVERSE EVENTS for BYETTA, including all such  
16 DOCUMENTS that compare BYETTA to any other therapeutic agent(s) for the  
17 treatment of type 2 diabetes. To the extent that such DOCUMENTS were prepared  
18 in color, they should also be produced in color.

19 **RESPONSE TO REQUEST NO. 43:**

20 Subject to the Preliminary Statement, Amylin objects to this Request as  
21 duplicative of Requests Nos. 39, 40, and 41. Amylin further objects to this Request  
22 as not reasonably calculated to lead to the discovery of admissible evidence, unduly  
23 burdensome, and overbroad, and on the grounds that the likely benefit, if any, of the  
24 discovery is outweighed by the substantial burdens of production. Adverse event  
25 reports are used in the generation of scientific hypotheses, and cannot establish a  
26 causal association between a pharmaceutical or biologic agent and a condition, and  
27 are therefore of little or no value in this litigation.

28 Amylin further objects to this Request as overbroad and not reasonably

1 calculated to lead to the discovery of admissible information to the extent it seeks  
2 information about pancreatitis adverse events. The Court's March 25, 2014 order  
3 limited discovery in this phase to "general causation on the link between the  
4 Defendants' pharmaceuticals and *pancreatic cancer*." 3/25/2014 Order at 3:6-7  
5 (emphasis added). Amylin will only produce documents related to pancreatitis as  
6 part of its attempt to make a comprehensive production of information relating to  
7 the general causation concerning pancreatic cancer, and specifically objects to any  
8 obligation to separately search for or produce information about pancreatitis  
9 adverse events.

10 Amylin further objects to the Request to the extent it seeks the production of  
11 information that would compromise the privacy of the patients, health care  
12 providers, reporters, or other persons identified in data concerning specific adverse  
13 events. Such information is absolutely protected by federal regulation, and Amylin  
14 is not at liberty to disclose it to Plaintiffs. *See* 21 C.F.R. § 20.63.

15 Amylin further objects to this Request to the extent it seeks the production of  
16 documents relating to reported events regarding non-plaintiffs because the burden  
17 and expense of production outweighs the likelihood those documents will lead to  
18 relevant evidence.

19 Amylin further objects to the extent the Request assumes or suggests that  
20 Amylin associated a given Adverse Event Report with Byetta®. Amylin's  
21 responsibility is to record and store Adverse Events Reports that are brought to its  
22 attention by reporters, who are in most instances not Amylin employees, under no  
23 obligation to provide Amylin accurate or complete information, and may lack  
24 sufficient information or qualification to associate an Adverse Event with a  
25 pharmaceutical or biological agent. Amylin objects to any Request that  
26 characterizes the mandated recording and reporting of Adverse Events Reports as  
27 an admission of causation, association, or any other relationship.

28 Subject to and without waiving the foregoing objections, Amylin responds as

1 follows: Amylin refers Plaintiffs to the documents previously produced in this  
2 litigation, including without limitation the Byetta® IND/NDA (Bates numbers  
3 BY00000001-BY00449028), which includes PSURs; and files of custodians  
4 involved in post-market surveillance. A spreadsheet identifying the Bates numbers  
5 associated with a given custodian is attached as Exhibit D.

6 Amylin further refers Plaintiffs to the document beginning at Bates number  
7 AMYLN03845763, produced on May 2, 2014.

8 Amylin further responds that it is concurrently producing an updated  
9 Byetta® IND/NDA and files for custodians as negotiated with Plaintiffs.  
10 Following a reasonable search, Amylin will produce nonprivileged documents  
11 found in the custodial files that are responsive to this Request. All such searches  
12 and subsequent productions will be governed by the Federal Rules of Civil  
13 Procedure, applicable orders in this case, and any agreements between Amylin and  
14 Plaintiffs.

15 **REQUEST NO. 44:**

16 All reports, memoranda and other DOCUMENTS that list and/or explain the  
17 criteria YOU use to determine whether any particular pancreatitis and/or pancreatic  
18 cancer ADVERSE EVENT is related to the patient's use of BYETTA.

19 **RESPONSE TO REQUEST NO. 44:**

20 Subject to the Preliminary Statement, Amylin further objects to this Request  
21 as not reasonably calculated to lead to the discovery of admissible evidence, unduly  
22 burdensome, and overbroad, and on the grounds that the likely benefit, if any, of the  
23 discovery is outweighed by the substantial burdens of production. Adverse event  
24 reports are used in the generation of scientific hypotheses, and cannot establish a  
25 causal association between a pharmaceutical or biologic agent and a condition, and  
26 are therefore of little or no value in this litigation.

27 Amylin further objects to this Request as overbroad and not reasonably  
28 calculated to lead to the discovery of admissible information to the extent it seeks

1 information about pancreatitis adverse events. The Court's March 25, 2014 order  
2 limited discovery in this phase to "general causation on the link between the  
3 Defendants' pharmaceuticals and *pancreatic cancer*." 3/25/2014 Order at 3:6-7  
4 (emphasis added). Amylin will only produce documents related to pancreatitis as  
5 part of its attempt to make a comprehensive production of information relating to  
6 general causation concerning pancreatic cancer, and specifically objects to any  
7 obligation to separately search for or produce information about pancreatitis.

8 Amylin further objects to the extent the Request assumes or suggests that  
9 Amylin associated a given Adverse Event Report with Byetta®. Amylin's  
10 responsibility is to record and store Adverse Events Reports that are brought to its  
11 attention by reporters, who are in most instances not Amylin employees, under no  
12 obligation to provide Amylin accurate or complete information, and may lack  
13 sufficient information or qualification to associate an Adverse Event with a  
14 pharmaceutical or biological agent. Amylin objects to any Request that  
15 characterizes the mandated recording and reporting of Adverse Events Reports as  
16 an admission of causation, association, or any other relationship.

17 Subject to and without waiving the foregoing objections, Amylin responds as  
18 follows: Amylin refers Plaintiffs to documents previously produced in this  
19 litigation, including without limitation Bristol-Myers Squibb Global  
20 Pharmacovigilance and Epidemiology Standard Operating Procedures produced on  
21 February 7, 2014 (AMYLN03838852-AMYLN03839761); Bristol-Myers Squibb  
22 Global Pharmacovigilance and Epidemiology Training Materials produced on  
23 February 8, 2014 (AMYLN03839777-AMYLN03842921); historical Amylin  
24 pharmacovigilance Standard Operating Procedures produced on February 13, 2014  
25 (AMYLN03842922-AMYLN03843892); Amylin's supplemental historical  
26 standard operating procedures produced on May 2, 2014 (AMYLN03844175-  
27 AMYLN03844331 and AMYLN03845162-AMYLN03845162-  
28

1 AMYLN03845340); and Amylin's training materials produced on May 2, 2014  
2 (AMYLN03844332-AMYLN03845161).

3 **REQUEST NO. 45:**

4 All medical and scientific literature that YOUR company has identified that  
5 relates to the association between BYETTA or any other GLP-1 agonist or DPP-4  
6 inhibitor and pancreatitis and/or pancreatic cancer.

7 **RESPONSE TO REQUEST NO. 45:**

8 Subject to the Preliminary Statement, Amylin objects to this Request on the  
9 grounds that it seeks documents publicly and equally available to Plaintiffs and on  
10 the grounds it seeks documents not within Amylin's custody and control.

11 Amylin further objects to the Request overbroad, oppressive and unduly  
12 burdensome to the extent that it seeks information about drugs other than Byetta®  
13 and exenatide in litigation that, as it applies to Amylin, only concerns claims related  
14 to Byetta®. Amylin further objects to the Request as irrelevant and not reasonably  
15 calculated to lead to the discovery of admissible evidence to the extent it seeks  
16 information about an association between Byetta® and pancreatitis; the Court's  
17 March 25, 2014 order limited discovery in this phase to "general causation on the  
18 link between the Defendants' pharmaceuticals and *pancreatic cancer*." 3/25/2014  
19 Order at 3:6-7 (emphasis added). Amylin will only produce documents related to  
20 pancreatitis as part of its attempt to make a comprehensive production of  
21 information relating to general causation of pancreatic cancer, and specifically  
22 objects to any obligation to separately search for or produce information about  
23 pancreatitis.

24 Amylin further objects to the Request as vague and ambiguous, including  
25 but not limited to its term "that relates to the association."

26 Amylin further objects to the Request as premature on the grounds that it  
27 calls for expert opinion as to what "medical and scientific literature . . . relates to  
28 the association between BYETTA or any other GLP-1 agonist or DPP-4 inhibitor



1 and pancreatitis and/or pancreatic cancer.” Amylin will produce its experts’  
2 opinions in accordance with the schedule to be established by the Court.

3 Subject to and without waiving the foregoing objections, Amylin responds as  
4 follows: Medical and scientific literature about Byetta® can be found in the  
5 Byetta® IND/NDA Amylin produced to Plaintiffs on December 12, 2012 (Bates  
6 numbers BY00000001-BY00449028) and in the supplemental Byetta® IND/NDA  
7 included in Amylin’s concurrent production. Amylin also refers Plaintiffs to the  
8 custodial files produced to Plaintiffs on December 21, 2012, March 8, 2013, and  
9 October 4, 2013, and custodial files in its upcoming production as negotiated with  
10 Plaintiffs. Following a reasonable search, Amylin will produce nonprivileged  
11 documents found in the custodial files that are responsive to this Request. All such  
12 searches and subsequent productions will be governed by the Federal Rules of Civil  
13 Procedure, applicable orders in this case, and any agreements between Amylin and  
14 Plaintiffs. Attached as Exhibit D is a spreadsheet listing the custodians whose files  
15 have previously been produced, the custodians’ job titles, and the Bates numbers  
16 containing each custodian’s files. Plaintiffs can identify documents responsive to  
17 this Request within these productions or from public sources as readily as Amylin  
18 could.

19 **REQUEST NO. 46:**

20 All reports, analyses, presentations, memoranda and other DOCUMENTS  
21 YOU are aware of that address, in whole or in part, whether BYETTA or any other  
22 GLP-1 agonist or DPP-4 inhibitor CAUSES and/or is capable of CAUSING  
23 pancreatitis and/or pancreatic cancer.

24 **RESPONSE TO REQUEST NO. 46:**

25 Subject to the Preliminary Statement, Amylin objects to this Request on the  
26 grounds that it seeks documents publicly and equally available to Plaintiffs and on  
27 the grounds it seeks documents not within Amylin’s custody and control. Amylin  
28 further objects to the Request as overbroad, irrelevant and not reasonably calculated

1 to lead to the discovery of admissible evidence related to general causation to the  
2 extent it seeks “[a]ll reports, analyses, presentations, memoranda and other  
3 DOCUMENTS” without regard to whether the documents constitute scientific data  
4 or evidence. The Court’s March 25, 2014 order provides that “permitted discovery  
5 includes *actual scientific evidence* . . . with regard to the causal link in dispute in  
6 this case.” 3/25/2014 Order at 2:20-23 (emphasis added).

7 Amylin further objects to the Request as overbroad, oppressive and unduly  
8 burdensome to the extent that it seeks information about drugs other than Byetta®  
9 and exenatide in litigation that, as it applies to Amylin, only concerns claims related  
10 to Byetta®. Amylin further objects to the Request as irrelevant and not reasonably  
11 calculated to lead to the discovery of admissible evidence to the extent it seeks  
12 information about a causal relationship between Byetta®, GLP-1 agonists and DPP-  
13 4 inhibitors and pancreatitis. The Court’s March 25, 2014 order limited discovery  
14 in this phase to “general causation on the link between the Defendants’  
15 pharmaceuticals and *pancreatic cancer*.” 3/25/2014 Order at 3:6-7 (emphasis  
16 added). Amylin will only produce documents related to pancreatitis as part of its  
17 attempt to make a comprehensive production of information relating to general  
18 causation of pancreatic cancer, and specifically objects to any obligation to  
19 separately search for or produce information about pancreatitis.

20 Amylin further objects to the Request as vague and ambiguous, including  
21 but not limited to its term “is capable of CAUSING.”

22 Subject to and without waiving the foregoing objections, Amylin responds as  
23 follows: Byetta® study reports can be found in the Byetta® IND/NDA Amylin  
24 produced to Plaintiffs on December 12, 2012 (Bates numbers BY00000001-  
25 BY00449028) and in the supplemental Byetta® IND/NDA included in Amylin’s  
26 concurrent production. Amylin also refers Plaintiffs to the custodial files produced  
27 to Plaintiffs on December 21, 2012, March 8, 2013, and October 4, 2013, and to the  
28 custodial files to be included in Amylin’s forthcoming productions as negotiated

1 with Plaintiffs. Following a reasonable search, Amylin will produce nonprivileged  
2 documents found in the custodial files that are responsive to this Request. All such  
3 searches and subsequent productions will be governed by the Federal Rules of Civil  
4 Procedure, applicable orders in this case, and any agreements between Amylin and  
5 Plaintiffs. Attached as Exhibit D is a spreadsheet listing the custodians whose  
6 files have previously been produced, the custodians' job titles, and the Bates  
7 numbers containing each custodian's files. Plaintiffs can locate and identify  
8 documents responsive to this Request within these productions as readily as Amylin  
9 could. Amylin further refers Plaintiffs to the document beginning at Bates number  
10 AMYLN03845763, produced on May 2, 2014.

11 **REQUEST NO. 47:**

12 To the extent not already produced in response to the preceding requests, all  
13 published and unpublished medical and scientific literature, reports, analyses,  
14 presentations, memoranda and other DOCUMENTS YOU are aware of that address  
15 whether BYETTA or any other GLP-1 agonist or DPP-4 inhibitor CAUSES the  
16 proliferation of abnormal or dysfunctional beta cells; the proliferation of abnormal  
17 or dysfunctional alpha cells; the expansion of pancreatic ductal glands in rats; the  
18 formation of dysplastic lesions and chronic pancreatitis in mice; increases in the  
19 weight and/or size of the exocrine pancreas; the inhibition of apoptosis of  
20 pancreatic ductal cells; and the inhibition of apoptosis of pancreatic islet cells.

21 **RESPONSE TO REQUEST NO. 47:**

22 Subject to the Preliminary Statement, Amylin objects to this Request as  
23 overbroad and unduly burdensome, including but not limited to its request for "all  
24 published and unpublished medical and scientific literature, reports, analyses,  
25 presentations, memoranda and other DOCUMENTS YOU are aware of" without  
26 limitation as to time or expertise. Amylin further objects to the Request on the  
27 grounds that it seeks documents publicly and equally available to Plaintiffs and on  
28 the grounds it seeks documents not within Amylin's custody and control.

1 Amylin further objects to the Request as overbroad, oppressive and unduly  
2 burdensome to the extent that it seeks information about drugs other than Byetta®  
3 and exenatide in litigation that, as it applies to Amylin, only concerns claims related  
4 to Byetta®.

5 Subject to and without waiving the foregoing objections, Amylin responds as  
6 follows: Byetta® study reports can be found in the Byetta® IND/NDA Amylin  
7 produced to Plaintiffs on December 12, 2012 (Bates numbers BY000000001-  
8 BY00449028) and in the supplemental Byetta® IND/NDA to be included in  
9 Amylin's forthcoming productions. Amylin also refers Plaintiffs to the custodial  
10 files produced to Plaintiffs on December 21, 2012, March 8, 2013, and October 4,  
11 2013, and to the custodial files to be included in Amylin's forthcoming productions  
12 as negotiated with Plaintiffs. Following a reasonable search, Amylin will produce  
13 nonprivileged documents found in the custodial files that are responsive to this  
14 Request. All such searches and subsequent productions will be governed by the  
15 Federal Rules of Civil Procedure, applicable orders in this case, and any agreements  
16 between Amylin and Plaintiffs. Attached as Exhibit D is a spreadsheet listing the  
17 custodians whose files have previously been produced, the custodians' job titles,  
18 and the Bates numbers containing each custodian's files. Plaintiffs can locate and  
19 identify documents responsive to this Request within these productions as readily  
20 as Amylin could.

21 **REQUEST NO. 48:**

22 To the extent not already produced in response to the preceding requests, all  
23 published and unpublished medical and scientific literature, reports, analyses,  
24 presentations, memoranda and other DOCUMENTS YOU are aware of that address  
25 the mechanism of action of BYETTA or any other GLP-1 agonist or DPP-4  
26 inhibitor.

27 **RESPONSE TO REQUEST NO. 48:**

28 Subject to the Preliminary Statement, Amylin objects to this Request as

1 overbroad and unduly burdensome, including but not limited to its request for “all  
2 published and unpublished medical and scientific literature, reports, analyses,  
3 presentations, memoranda and other DOCUMENTS YOU are aware of” without  
4 limitation as to time or expertise. Amylin further objects to the Request on the  
5 grounds that it seeks documents publicly and equally available to Plaintiffs and on  
6 the grounds it seeks documents not within Amylin’s custody and control.

7 Amylin further objects to the Request as overbroad, oppressive and unduly  
8 burdensome to the extent that it seeks information about drugs other than Byetta®  
9 and exenatide in litigation that, as it applies to Amylin, only concerns claims related  
10 to Byetta®.

11 Subject to and without waiving the foregoing objections, Amylin responds as  
12 follows: Byetta® study reports can be found in the Byetta® IND/NDA Amylin  
13 produced to Plaintiffs on December 12, 2012 (Bates numbers BY00000001-  
14 BY00449028) and in the supplemental Byetta® IND/NDA included in Amylin’s  
15 concurrent production. Amylin also refers Plaintiffs to the custodial files produced  
16 to Plaintiffs on December 21, 2012, March 8, 2013, and October 4, 2013, and to the  
17 custodial files to be included in Amylin’s forthcoming productions as negotiated  
18 with Plaintiffs. Following a reasonable search, Amylin will produce nonprivileged  
19 documents found in the custodial files that are responsive to this Request. All such  
20 searches and subsequent productions will be governed by the Federal Rules of Civil  
21 Procedure, applicable orders in this case, and any agreements between Amylin and  
22 Plaintiffs. Attached as Exhibit D is a spreadsheet listing the custodians whose  
23 files have previously been produced, the custodians’ job titles, and the Bates  
24 numbers containing each custodian’s files. Plaintiffs can locate and identify  
25 documents responsive to this Request within these productions as readily as Amylin  
26 could.

27 **REQUEST NO. 49:**

28 To the extent not already produced in response to the preceding requests, all

1 published and unpublished medical and scientific literature, reports, analyses,  
2 presentations, memoranda and other DOCUMENTS YOU are aware of that address  
3 the effect that BYETTA or any other GLP-1 agonist or DPP-4 inhibitor has on the  
4 pancreas.

5 **RESPONSE TO REQUEST NO. 49:**

6 Subject to the Preliminary Statement, Amylin objects to this Request as  
7 overbroad and unduly burdensome, including but not limited to its request for “all  
8 published and unpublished medical and scientific literature, reports, analyses,  
9 presentations, memoranda and other DOCUMENTS YOU are aware of” without  
10 limitation as to time or expertise. Amylin further objects to the Request on the  
11 grounds that it seeks documents publicly and equally available to Plaintiffs and on  
12 the grounds it seeks documents not within Amylin’s custody and control.

13 Amylin further objects to the Request as overbroad, oppressive and unduly  
14 to the extent that it seeks information about drugs other than Byetta® and exenatide  
15 in litigation that, as it applies to Amylin, only concerns claims related to Byetta®.

16 Subject to and without waiving the foregoing objections, Amylin responds as  
17 follows: Byetta® study reports can be found in the Byetta® IND/NDA Amylin  
18 produced to Plaintiffs on December 12, 2012 (Bates numbers BY000000001-  
19 BY00449028) and in the supplemental Byetta® IND/NDA included in Amylin’s  
20 concurrent productions. Amylin also refers Plaintiffs to the custodial files produced  
21 to Plaintiffs on December 21, 2012, March 8, 2013, and October 4, 2013, and to the  
22 custodial files to be included in Amylin’s forthcoming productions as negotiated  
23 with Plaintiffs. Following a reasonable search, Amylin will produce nonprivileged  
24 documents found in the custodial files that are responsive to this Request. All such  
25 searches and subsequent productions will be governed by the Federal Rules of Civil  
26 Procedure, applicable orders in this case, and any agreements between Amylin and  
27 Plaintiffs. Attached as Exhibit D is a spreadsheet listing the custodians whose files  
28 have previously been produced, the custodians’ job titles, and the Bates numbers

1 containing each custodian's files. Plaintiffs can locate and identify documents  
2 responsive to this Request within these productions as readily as Amylin could.

3 **REQUEST NO. 50:**

4 All reports, memoranda and other DOCUMENTS that list and/or explain the  
5 criteria YOU use to determine whether BYETTA or any other GLP-1 agonist or  
6 DPP-4 inhibitor CAUSES and/or is capable of CAUSING pancreatitis and/or  
7 pancreatic cancer.

8 **RESPONSE TO REQUEST NO. 50:**

9 Subject to the Preliminary Statement, Amylin objects to this Request as  
10 overbroad, oppressive and unduly burdensome on the grounds that it seeks "[a]ll  
11 reports, memoranda and other DOCUMENTS," without limitation, and it seeks  
12 information about drugs other than Byetta® or exenatide in litigation that, as it  
13 applies to Amylin, concerns only claims related to Byetta®.

14 Amylin further objects to the Request as not reasonably calculated to lead to  
15 the discovery of admissible evidence to the extent it seeks information about  
16 criteria used to determine "whether BYETTA or any other GLP-1 agonist or DPP-4  
17 inhibitor CAUSES and/or is capable of CAUSING pancreatitis." The Court's  
18 March 25, 2014 order limited discovery in this phase to "general causation on the  
19 link between the Defendants' pharmaceuticals and *pancreatic cancer*." 3/25/2014  
20 Order at 3:6-7 (emphasis added). Amylin will only produce documents related to  
21 pancreatitis as part of its attempt to make a comprehensive production of  
22 information relating to general causation concerning pancreatic cancer, and  
23 specifically objects to any obligation to separately search for or produce  
24 information about pancreatitis.

25 Amylin further objects to the Request to the extent it suggests there is a  
26 causal connection between Byetta® and pancreatic cancer. Amylin further objects  
27 to the Request on the grounds that it calls for expert opinion. Amylin will disclose  
28 its experts' opinions in accordance with the schedule to be set by the Court.

1 Subject to and without waiving the foregoing objections, Amylin responds as  
2 follows: Amylin refers Plaintiffs to its prior productions, including without  
3 limitation the memorandum beginning at Bates number AMYLN03845763, and the  
4 custodial files produced to Plaintiffs on December 21, 2012, March 8, 2013, and  
5 October 4, 2013. Attached as Exhibit D is a spreadsheet listing the custodians  
6 whose files have previously been produced, the custodians' job titles, and the Bates  
7 numbers containing each custodian's files. Plaintiffs can locate and identify  
8 documents responsive to this Request within these productions as readily as Amylin  
9 could. Amylin further refers Plaintiffs to the custodial files to be included in  
10 Amylin's forthcoming productions as negotiated with Plaintiffs.

11 Amylin further responds that it will conduct a reasonable search for  
12 additional responsive documents in its possession, custody or control. Amylin will  
13 produce nonprivileged documents found in that search that are responsive to this  
14 Request. All such searches and subsequent productions will be governed by the  
15 Federal Rules of Civil Procedure, applicable orders in this case, and any agreements  
16 between Amylin and Plaintiffs. Amylin refers Plaintiffs to the document beginning  
17 at Bates number AMYLN03845763, produced on May 2, 2014.

18 **REQUEST NO. 51:**

19 All medical and/or scientific literature that YOU have reported to the FDA or  
20 any other regulatory authorities that relates to the association between BYETTA  
21 and pancreatitis and/or pancreatic cancer, including, but not limited to, all PSURs,  
22 PADERS/PAERS, and independent submissions.

23 **RESPONSE TO REQUEST NO. 51:**

24 Subject to the Preliminary Statement, Amylin objects to this Request on the  
25 grounds that it seeks documents publicly and equally available to Plaintiffs and on  
26 the grounds it seeks documents not within Amylin's custody and control. Amylin  
27 further objects to the Request as vague and ambiguous, including without limitation  
28 its terms "that relates to the association between BYETTA and pancreatitis and/or



1 pancreatic cancer” and “independent submissions.”

2 Amylin further objects to the Request as not reasonably calculated to lead to  
3 the discovery of admissible evidence to the extent it seeks information about an  
4 association between Byetta® and pancreatitis; the Court’s March 25, 2014 order  
5 limited discovery in this phase to “general causation on the link between the  
6 Defendants’ pharmaceuticals and *pancreatic cancer*.” 3/25/2014 Order at 3:6-7  
7 (emphasis added). Amylin will only produce documents related to pancreatitis as  
8 part of its attempt to make a comprehensive production of information relating to  
9 general causation of pancreatic cancer, and specifically objects to any obligation to  
10 separately search for or produce information about pancreatitis.

11 Amylin further objects to the Request to the extent it seeks information  
12 related to Amylin’s communications with regulatory agencies outside the United  
13 States, as all relevant events in this litigation occurred within the United States.

14 Subject to and without waiving the foregoing objections, Amylin responds as  
15 follows: Medical and scientific literature about Byetta® can be found in the  
16 Byetta® IND/NDA Amylin produced to Plaintiffs on December 12, 2012 (Bates  
17 numbers BY00000001-BY00449028) and in the supplemental Byetta® IND/NDA  
18 included in Amylin’s concurrent production. Amylin also refers Plaintiffs to the  
19 custodial files produced to Plaintiffs on December 21, 2012, March 8, 2013, and  
20 October 4, 2013, and to the custodial files to be included in Amylin’s forthcoming  
21 productions as negotiated with Plaintiffs. Following a reasonable search, Amylin  
22 will produce nonprivileged documents found in the custodial files that are  
23 responsive to this Request. All such searches and subsequent productions will be  
24 governed by the Federal Rules of Civil Procedure, applicable orders in this case,  
25 and any agreements between Amylin and Plaintiffs. Attached as Exhibit D is a  
26 spreadsheet listing the custodians whose files have previously been produced, the  
27 custodians’ job titles, and the Bates numbers containing each custodian’s files.  
28 Plaintiffs can identify documents responsive to this Request within these

1 productions as readily as Amylin could.

2 Amylin further refers Plaintiffs to EMA files to be included in Amylin's and  
3 Lilly's forthcoming productions. Amylin agrees to produce the EMA files under  
4 the unique and specific facts of this case – namely, that Amylin has noted the  
5 EMA's July 2013 conclusion that Byetta® and other incretin-based therapies do not  
6 cause pancreatic cancer, as well as the February 2014 statement jointly authored by  
7 the EMA and the FDA that rejects the hypothesized associations between  
8 pancreatic cancer and Byetta® and other incretin therapies that underlie Plaintiffs'  
9 claims. Amylin continues to maintain that regulatory filings with foreign agencies  
10 are irrelevant to products liability actions in the United States and generally should  
11 not be produced in such litigation.

12 **REQUEST NO. 52:**

13 To the extent not already produced in response to the preceding requests,  
14 produce all communications, analyses, expert analyses, safety board analyses,  
15 independent analyses, and/or meta-analyses that pertain to, reference, or in any way  
16 discuss any of the medical and scientific literature and/or the preclinical,  
17 nonclinical, animal, human, observational and/or other studies referred to above  
18 with respect to whether BYETTA or any other GLP-1 agonist or DPP-4 inhibitor  
19 CAUSES and/or is capable of CAUSING pancreatitis and/or pancreatic cancer.

20 **RESPONSE TO REQUEST NO. 52:**

21 Subject to the Preliminary Statement, Amylin objects to this Request as  
22 duplicative of Requests Nos. 45, 46 and 49. Amylin refers Plaintiffs to its  
23 objections and responses to Requests No. 45, 46 and 49, which are incorporated by  
24 reference as if set forth fully here.

25 **REQUEST NO. 53:**

26 All communications YOU have had with the author(s) of the medical and/or  
27 scientific literature referenced above with respect to whether BYETTA or any other  
28 GLP-1 agonist or DPP-4 inhibitor CAUSES and/or is capable of CAUSING

1 pancreatic cancer.

2 **RESPONSE TO REQUEST NO. 53:**

3 Subject to the Preliminary Statement, Amylin further objects to the Request  
4 as irrelevant and not reasonably calculated to lead to the discovery of admissible  
5 evidence to the extent it seeks information other than scientific evidence. The  
6 Court's March 25, 2014 order provides that "permitted discovery includes *actual*  
7 *scientific evidence* . . . with regard to the causal link in dispute in this case."  
8 3/25/2014 Order at 2:20-23 (emphasis added). The relevance or competence of  
9 evidence on general causation is not dependent on the persons to whom it was  
10 communicated. To the extent this Request seeks evidence that is relevant to general  
11 causation, it is duplicative of Plaintiffs' other requests that seek such evidence more  
12 directly.

13 Amylin further objects to the Request as overbroad and unduly burdensome  
14 to the extent that it seeks information about drugs other than Byetta® or exenatide  
15 in litigation that, as it applies to Amylin, concerns only claims related to Byetta®.

16 Amylin further objects to the Request as vague and ambiguous, including but  
17 not limited to its term "is capable of CAUSING."

18 Subject to and without waiving the foregoing objections, Amylin responds as  
19 follows: Amylin refers Plaintiffs to the custodial files produced to Plaintiffs on  
20 December 21, 2012, March 8, 2013, and October 4, 2013, and to the custodial files  
21 to be included in Amylin's forthcoming production as negotiated with Plaintiffs.  
22 Following a reasonable search, Amylin will produce any nonprivileged documents  
23 found in the custodial files that are responsive to this Request. All such searches  
24 and subsequent productions will be governed by the Federal Rules of Civil  
25 Procedure, applicable orders in this case, and any agreements between Amylin and  
26 Plaintiffs. Attached as Exhibit D is a spreadsheet listing the custodians whose files  
27 have previously been produced, the custodians' job titles, and the Bates numbers  
28 containing each custodian's files. Plaintiffs can locate and identify documents

responsive to this Request within these productions as readily as Amylin could.

**REQUEST NO. 54:**

All emails, letters, reports, memoranda and other written communications YOU have had internally regarding whether BYETTA or any other GLP-1 agonist or DPP-4 inhibitor CAUSES and/or is capable of CAUSING pancreatic cancer.

**RESPONSE TO REQUEST NO. 54:**

Subject to the Preliminary Statement, Amylin objects to this Request as overbroad, irrelevant and not reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks communications other than scientific data. The Court's March 25, 2014 order provides that "permitted discovery includes *actual scientific evidence* . . . with regard to the causal link in dispute in this case." 3/25/2014 Order at 2:20-23 (emphasis added).

Amylin further objects to the Request as overbroad and unduly burdensome to the extent that it seeks information about drugs other than Byetta® or exenatide in litigation that, as it applies to Amylin, concerns only claims related to Byetta®.

Amylin further objects to the Interrogatory as vague and ambiguous, including but not limited to its term "is capable of CAUSING."

Amylin further objects to this Request to the extent it seeks documents and information protected by the attorney-client privilege and/or attorney work product doctrine.

Subject to and without waiving the foregoing objections, Amylin responds as follows: Amylin refers Plaintiffs to the custodial files produced to Plaintiffs on December 21, 2012, March 8, 2013, and October 4, 2013, and to the custodial files to be included in Amylin's forthcoming production as negotiated with Plaintiffs. Following a reasonable search, Amylin will produce nonprivileged documents found in the custodial files that are responsive to this Request. All such searches and subsequent productions will be governed by the Federal Rules of Civil Procedure, applicable orders in this case, and any agreements between Amylin and

1 Plaintiffs. Attached as Exhibit D is a spreadsheet listing the custodians whose files  
2 have previously been produced, the custodians' job titles, and the Bates numbers  
3 containing each custodian's files. Plaintiffs can locate and identify documents  
4 responsive to this Interrogatory within these productions as readily as Amylin  
5 could.

6 **REQUEST NO. 55:**

7 If YOU have made and/or requested label changes in the United States or  
8 elsewhere to add or strengthen warnings about the risks of pancreatitis and/or  
9 pancreatic cancer associated with BYETTA at any time since YOU began to market  
10 BYETTA, provide all DOCUMENTS, including emails, letters, reports,  
11 memoranda and other written communications, that YOU have sent to or received  
12 from the FDA and/or any applicable foreign country's regulatory authority in  
13 connection with each label change and/or request. This request to produce includes,  
14 without limitation, any PAS or CBE submitted by YOU to the FDA, and any  
15 response YOU have received from the FDA.

16 **RESPONSE TO REQUEST NO. 55:**

17 Subject to the Preliminary Statement, Amylin objects to this Request as  
18 irrelevant and not reasonably calculated to lead to the discovery of admissible  
19 evidence in that information and communications about label changes do not  
20 constitute data relevant to general causation. The Court's March 25, 2014 order  
21 provides that "permitted discovery includes *actual scientific evidence* . . . with  
22 regard to the causal link in dispute in this case." 3/25/2014 Order at 2:20-23  
23 (emphasis added). Amylin further objects to the Request as irrelevant and not  
24 reasonably calculated to lead to the discovery of admissible evidence to the extent it  
25 seeks information about label changes pertaining to pancreatitis. The Court's  
26 March 25, 2014 order limited discovery in this phase to "general causation on the  
27 link between the Defendants' pharmaceuticals and *pancreatic cancer*." *Id.* at 3:6-7  
28 (emphasis added). Amylin will only produce documents related to pancreatitis as

1 part of its attempt to make a comprehensive production of information relating to  
2 general causation concerning pancreatic cancer, and specifically objects to any  
3 obligation to separately search for or produce information about pancreatitis.

4 Amylin further objects to the Request as irrelevant and not reasonably  
5 calculated to lead to the discovery of admissible evidence to the extent it seeks  
6 information about communications with regulatory agencies outside the United  
7 States as all relevant events in these cases occurred in the United States.

8 Subject to and without waiving the foregoing objections, Amylin responds as  
9 follows: Amylin has not made and/or requested label changes in the United States  
10 to add or strengthen warnings about the risks of pancreatic cancer associated with  
11 Byetta® at any time since it began to market Byetta®.

12 **REQUEST NO. 56:**

13 All emails, letters, reports, memoranda and other written communications to  
14 or from any source discussing or referring to physician monitoring and/or testing  
15 for pancreatitis and/or pancreatic cancer associated with the use of BYETTA.

16 **RESPONSE TO REQUEST NO. 56:**

17 Subject to the Preliminary Statement, Amylin objects this Request as  
18 overbroad and unduly burdensome, and on the grounds that the burden of  
19 production far outweigh the likely benefit of the production. Amylin further objects  
20 to this Request as not reasonably calculated to lead to the discovery of admissible  
21 evidence to the extent the sought after communications about physician monitoring  
22 and testing do not constitute scientific data. The Court's March 25, 2014 order  
23 provides that "permitted discovery includes *actual scientific evidence* . . . with  
24 regard to the causal link in dispute in this case." 3/25/2014 Order at 2:20-23  
25 (emphasis added). Amylin further objects to the Request as vague and ambiguous,  
26 including but not limited to its term "physician monitoring."

27 Amylin further objects to the Request as irrelevant and not reasonably  
28 calculated to lead to the discovery of admissible evidence to the extent it seeks

1 information about “physician monitoring and/or testing for pancreatitis.” The  
2 Court’s March 25, 2014 order limited discovery in this phase to “general causation  
3 on the link between the Defendants’ pharmaceuticals and *pancreatic cancer*.” *Id.*  
4 at 3:6-7 (emphasis added). Amylin will only produce documents related to  
5 pancreatitis as part of its attempt to make a comprehensive production of  
6 information relating to general causation concerning pancreatic cancer, and  
7 specifically objects to any obligation to separately search for or produce  
8 information about pancreatitis.

9 Amylin further objects to the Request to the extent it seeks documents not  
10 within Amylin’s possession, custody or control.

11 Subject to and without waiving the foregoing objections, Amylin responds as  
12 follows: Amylin refers Plaintiffs to the custodial files produced to Plaintiffs on  
13 December 21, 2012, March 8, 2013, and October 4, 2013, and to the custodial files  
14 to be included in Amylin’s forthcoming productions as negotiated with Plaintiffs.  
15 Following a reasonable search, Amylin will produce nonprivileged documents  
16 found in the custodial files that are responsive to this Request. All such searches  
17 and subsequent productions will be governed by the Federal Rules of Civil  
18 Procedure, applicable orders in this case, and any agreements between Amylin and  
19 Plaintiffs. Attached as Exhibit D is a spreadsheet listing the custodians whose  
20 files have previously been produced, the custodians’ job titles, and the Bates  
21 numbers containing each custodian’s files. Plaintiffs can locate and identify  
22 documents responsive to this Request within these productions as readily as Amylin  
23 could.

24 **REQUEST NO. 57:**

25 The meeting minutes and any summaries of meeting minutes for each  
26 internal meeting at which YOU discussed whether BYETTA or any other GLP-1  
27 agonist or DPP-4 inhibitor CAUSES and/or is capable of CAUSING pancreatitis  
28 and/or pancreatic cancer.

1 **RESPONSE TO REQUEST NO. 57:**

2 Subject to the Preliminary Statement, Amylin objects to this Request as  
3 duplicative of Request No. 46. Amylin refers Plaintiffs to its objections and  
4 responses to Request No. 46 which are incorporated by reference as if set forth fully  
5 here.

6 **REQUEST NO. 58:**

7 All notes, recordings, handouts, materials and presentations YOU or YOUR  
8 employees are aware of that were made or obtained in connection with any  
9 meeting, conference or other event, internal or external, at which the subject of  
10 whether BYETTA or any other GLP-1 agonist or DPP-4 inhibitor CAUSES and/or  
11 is capable of CAUSING pancreatitis and/or pancreatic cancer was discussed.

12 **RESPONSE TO REQUEST NO. 58:**

13 Subject to the Preliminary Statement, Amylin objects to this Request as  
14 duplicative of Request No. 46. Amylin refers Plaintiffs to its objections and  
15 responses to Request No. 46 which are incorporated by reference as if set forth fully  
16 here.

17 **REQUEST NO. 59:**

18 If the sale of BYETTA has ever been prohibited due to concerns that it may  
19 CAUSE pancreatitis and/or pancreatic cancer, produce all emails, letters, reports,  
20 memoranda and other written communications received by YOU addressing or  
21 discussing those concerns, and all emails, letters, reports, memoranda and other  
22 written communications prepared by YOU (whether sent or not sent) addressing or  
23 discussing those concerns.

24 **RESPONSE TO REQUEST NO. 59:**

25 Subject to the Preliminary Statement, Amylin objects to this Request as  
26 irrelevant and not reasonably calculated to lead to the discovery of admissible  
27 evidence to the extent it seeks information other than scientific data. The Court's  
28 March 25, 2014 order provides that "permitted discovery includes *actual scientific*



1 *evidence* . . . with regard to the causal link in dispute in this case.” 3/25/2014 Order  
2 at 2:20-23 (emphasis added). Amylin further objects to the Interrogatory to the  
3 extent it seeks information about the sale of Byetta® outside the United States as all  
4 relevant events in these cases occurred in the United States. Amylin further objects  
5 to the Request as vague and ambiguous, including without limitation its term  
6 “concerns.”

7 Amylin further objects to the Request as irrelevant and not reasonably  
8 calculated to lead to the discovery of admissible evidence to the extent it seeks  
9 information about “concerns that [Byetta®] may CAUSE pancreatitis.” The Court’s  
10 March 25, 2014 order limited discovery in this phase to “general causation on the  
11 link between the Defendants’ pharmaceuticals and *pancreatic cancer*.” *Id.* at 3:6-7  
12 (emphasis added). Amylin will only produce documents related to pancreatitis as  
13 part of its attempt to make a comprehensive production of information relating to  
14 general causation concerning pancreatic cancer, and specifically objects to any  
15 obligation to separately search for or produce information about pancreatitis.

16 Subject to and without waiving the foregoing objections, Amylin responds as  
17 follows: The sale of Byetta® has never been prohibited in the United States due to  
18 concerns that it may cause pancreatic cancer.

19 **REQUEST NO. 60:**

20 If any of YOUR employees, officers, directors, agents, contractors, key  
21 opinion leaders, members of speakers’ bureaus, advisory board members, or  
22 scientific advisors have corresponded with or supplied information or data to any  
23 scientific journal regarding whether BYETTA or any other GLP-1 agonist or DPP-  
24 4 inhibitor CAUSES and/or is capable of CAUSING pancreatitis and/or pancreatic  
25 cancer, produce the correspondence, information and/or data.

26 **RESPONSE TO REQUEST NO. 61:**

27 Subject to the Preliminary Statement, Amylin objects to this Request as  
28 overbroad, oppressive and unduly burdensome, and as seeking information outside

1 Amylin's custody and control, insofar as it seeks information about  
2 communications by Amylin's "agents, contractors, key opinion leaders, members of  
3 speakers' bureaus, advisory board members, and scientific advisors" as these  
4 persons are not Amylin employees, officers or directors, and to the extent the  
5 Request seeks information about communications by any persons not made in the  
6 course of their employment by or affiliation with Amylin.

7 Amylin further objects to the Request as irrelevant and not reasonably  
8 calculated to lead to the discovery of admissible evidence as the relevance or  
9 competence of evidence on general causation is not dependent on the entity or  
10 person to whom it was communicated. To the extent this Request seeks evidence  
11 that is relevant to general causation, it is duplicative of Plaintiffs' other requests  
12 that seek such evidence more directly.

13 Amylin further objects to the Request as overbroad and unduly burdensome  
14 to the extent that it seeks information about drugs other than Byetta® or exenatide  
15 in litigation that, as it applies to Amylin, concerns only claims related to Byetta®.  
16 Amylin further objects to the Request as irrelevant and not reasonably calculated to  
17 the lead to the discovery of admissible evidence insofar as it seeks information  
18 about "whether BYETTA or any other GLP-1 agonist or DPP-4 inhibitor CAUSES  
19 and/or is capable of CAUSING pancreatitis"; the Court's March 25, 2014 order  
20 limited discovery in this phase to "general causation on the link between the  
21 Defendants' pharmaceuticals and *pancreatic cancer*." 3/25/2014 Order at 3:6-7  
22 (emphasis added). Amylin will only produce documents related to pancreatitis as  
23 part of its attempt to make a comprehensive production of information relating to  
24 general causation concerning pancreatic cancer, and specifically objects to any  
25 obligation to separately search for or produce information about pancreatitis.

26 Amylin further objects to the Interrogatory as vague and ambiguous,  
27 including but not limited to its term "is capable of CAUSING."

28 Subject to and without waiving the foregoing objections, Amylin responds as

1 follows: Amylin refers Plaintiffs to the custodial files produced to Plaintiffs on  
2 December 21, 2012, March 8, 2013, and October 4, 2013, and to the custodial files  
3 to be included in Amylin's forthcoming productions as negotiated with Plaintiffs.  
4 Following a reasonable search, Amylin will produce nonprivileged documents  
5 found in the custodial files that are responsive to this Request. All such searches  
6 and subsequent productions will be governed by the Federal Rules of Civil  
7 Procedure, applicable orders in this case, and any agreements between Amylin and  
8 Plaintiffs. Attached as Exhibit D is a spreadsheet listing the custodians whose files  
9 have previously been produced and the Bates numbers containing each custodian's  
10 files. Plaintiffs can locate and identify documents responsive to this Request within  
11 these productions as readily as Amylin can.

12 **REQUEST NO. 61:**

13 If any of YOUR employees, officers, directors, agents, contractors, key  
14 opinion leaders, members of speakers' bureaus, advisory board members, or  
15 scientific advisors have submitted a manuscript, case report, article described as an  
16 "advertisement," opinion piece or topic to any scientific journal regarding whether  
17 BYETTA or any other GLP-1 agonist or DPP-4 inhibitor CAUSES and/or is  
18 capable of CAUSING pancreatitis and/or pancreatic cancer, produce the material  
19 submitted.

20 **RESPONSE TO REQUEST NO. 61:**

21 Subject to the Preliminary Statement, Amylin objects to this Request as  
22 overbroad, oppressive and unduly burdensome, and as seeking information outside  
23 Amylin's custody and control, insofar as it seeks information about submissions by  
24 Amylin's "agents, contractors, key opinion leaders, members of speakers' bureaus,  
25 advisory board members, and scientific advisors" as these persons are not Amylin  
26 employees, officers or directors, and to the extent the Request seeks information  
27 about submissions by any persons not made in the course of their employment by or  
28 affiliation with Amylin.

1 Amylin further objects to the Request as irrelevant and not reasonably  
2 calculated to lead to the discovery of admissible evidence as the relevance or  
3 competence of evidence on general causation is not dependent on the entity to  
4 which it was communicated. To the extent this Request seeks evidence that is  
5 relevant to general causation, it is duplicative of Plaintiffs' other requests that seek  
6 such evidence more directly.

7 Amylin further objects to the Request as overbroad, oppressive and unduly  
8 burdensome to the extent that it seeks information about drugs other than Byetta®  
9 or exenatide in litigation that, as it applies to Amylin, concerns only claims related  
10 to Byetta®. Amylin further objects to the Request as irrelevant and not reasonably  
11 calculated to the lead to the discovery of admissible evidence insofar as it seeks  
12 information about submissions "regarding whether BYETTA or any other GLP-1  
13 agonist or DPP-4 inhibitor CAUSES and/or is capable of CAUSING pancreatitis."  
14 The Court's March 25, 2014 order limited discovery in this phase to "general  
15 causation on the link between the Defendants' pharmaceuticals and *pancreatic*  
16 *cancer*." 3/25/2014 Order at 3:6-7 (emphasis added). Amylin will only produce  
17 documents related to pancreatitis as part of its attempt to make a comprehensive  
18 production of information relating to general causation concerning pancreatic  
19 cancer and specifically objects to any obligation to separately search for or produce  
20 information about pancreatitis.

21 Amylin further objects to the Interrogatory as vague and ambiguous,  
22 including but not limited to its term "is capable of CAUSING."

23 Subject to and without waiving the foregoing objections, Amylin responds as  
24 follows: Amylin refers Plaintiffs to the custodial files produced to Plaintiffs on  
25 December 21, 2012, March 8, 2013, and October 4, 2013, and to the custodial files  
26 to be included in Amylin's forthcoming productions as negotiated with Plaintiffs.  
27 Following a reasonable search, Amylin will produce nonprivileged documents  
28 found in the custodial files that are responsive to this Request. All such searches

1 and subsequent productions will be governed by the Federal Rules of Civil  
2 Procedure, applicable orders in this case, and any agreements between Amylin and  
3 Plaintiffs. Attached as Exhibit D is a spreadsheet listing the custodians whose files  
4 have previously been produced, the custodians' job titles, and the Bates numbers  
5 containing each custodian's files. Plaintiffs can locate and identify documents  
6 responsive to this Interrogatory within these productions as readily as Amylin can.

7 **REQUEST NO. 62:**

8 If any of YOUR employees, officers, directors, agents, contractors, key  
9 opinion leaders, members of speakers' bureaus, advisory board members, or  
10 scientific advisors have participated in or supplied information or data to any expert  
11 meeting, panel or committee investigating or reviewing whether BYETTA or any  
12 other GLP-1 agonist or DPP-4 inhibitor CAUSES and/or is capable of CAUSING  
13 pancreatitis and/or pancreatic cancer, produce the correspondence, data and other  
14 DOCUMENTS supplied to, received from, or created by such meeting(s), panel(s)  
15 or committee proceedings.

16 **RESPONSE TO REQUEST NO 62:**

17 Subject to the Preliminary Statement, Amylin objects to this Request as  
18 overbroad, oppressive and unduly burdensome, and as seeking information outside  
19 Amylin's custody and control, insofar as it seeks information about actions and  
20 documents by Amylin's "agents, contractors, key opinion leaders, members of  
21 speakers' bureaus, advisory board members, and scientific advisors" as these  
22 persons are not Amylin employees, officers or directors, and to the extent the  
23 Interrogatory seeks information about actions and documents by any persons not  
24 made in the course of their employment by or affiliation with Amylin.

25 Amylin further objects to the Request as irrelevant and not reasonably  
26 calculated to lead to the discovery of admissible evidence as the relevance or  
27 competence of evidence on general causation is not dependent on the entity to  
28 which it was communicated. To the extent this Request seeks evidence that is

1 relevant to general causation, it is duplicative of Plaintiffs' other requests that seek  
2 such evidence more directly.

3 Amylin further objects to the Request as overbroad, oppressive and unduly  
4 burdensome to the extent that it seeks information about drugs other than Byetta®  
5 or exenatide in litigation that, as it applies to Amylin, concerns only claims related  
6 to Byetta®. Amylin further objects to the Request as irrelevant and not reasonably  
7 calculated to the lead to the discovery of admissible evidence insofar as it seeks  
8 information about participation in and submissions to expert meetings, panels and  
9 committees "investigating or reviewing whether BYETTA or any other GLP-1  
10 agonist or DPP-4 inhibitor CAUSES and/or is capable of CAUSING pancreatitis."  
11 The Court's March 25, 2014 order limited discovery in this phase to "general  
12 causation on the link between the Defendants' pharmaceuticals and *pancreatic*  
13 *cancer*." 3/25/2014 Order at 3:6-7 (emphasis added). Amylin will only produce  
14 documents related to pancreatitis as part of its attempt to make a comprehensive  
15 production of information relating to general causation concerning pancreatic  
16 cancer, and specifically objects to any obligation to separately search for or produce  
17 information about pancreatitis.

18 Amylin further objects to the Interrogatory as vague and ambiguous,  
19 including but not limited to its term "is capable of CAUSING."

20 Subject to and without waiving the foregoing objections, Amylin responds as  
21 follows: Amylin refers Plaintiffs to the custodial files produced to Plaintiffs on  
22 December 21, 2012, March 8, 2013, and October 4, 2013, and to the custodial files  
23 to be included in Amylin's forthcoming productions as negotiated with Plaintiffs.  
24 Following a reasonable search, Amylin will produce nonprivileged documents  
25 found in the custodial files that are responsive to this Request. All such searches  
26 and subsequent productions will be governed by the Federal Rules of Civil  
27 Procedure, applicable orders in this case, and any agreements between Amylin and  
28 Plaintiffs. Attached as Exhibit D is a spreadsheet listing the custodians whose files

1 have previously been produced, the custodians' job titles, and the Bates numbers  
2 containing each custodian's files. Plaintiffs can locate and identify documents  
3 responsive to this Interrogatory within these productions as readily as Amylin can.

4 **REQUEST NO. 63:**

5 If any of YOUR employees, officers, directors, agents, contractors, key  
6 opinion leaders, members of speakers' bureaus, advisory board members, or  
7 scientific advisors corresponded with or supplied information or data to any  
8 authors, medical journals, scientific journals, any other publications, any diabetes  
9 research or research-funding organizations or persons affiliated with them, any  
10 scientific advisors, or any consultants about Dr. Susan Bonner-Weir, Dr. Alexandra  
11 E. Butler, Dr. Peter C. Butler, Dr. David D. Dore, Dr. Daniel J. Drucker, Dr.  
12 Michael Elashoff, Dr. Robert Elashoff, Dr. Edwin Gale, Dr. Rajesh Garg, Dr.  
13 Belinda Gier, Dr. Fred Gorlick, Dr. Steven Kahn, Dr. Jacqueline Koehler, Dr.  
14 Aleksey V. Matveyenko, Dr. Robert Ratner, Dr. Sonal Singh, or Dr. Jay S. Skyler,  
15 and/or about any of the work they have done or authored regarding incretin  
16 medications, produce the correspondence, information and/or data.

17 **RESPONSE TO REQUEST NO. 63:**

18 Subject to the Preliminary Statement, Amylin objects to this Request as  
19 overbroad, oppressive and unduly burdensome, and as seeking information outside  
20 Amylin's custody and control, insofar as it seeks information about  
21 communications by Amylin's "agents, contractors, key opinion leaders, members of  
22 speakers' bureaus, advisory board members, and scientific advisors" as these  
23 persons are not Amylin employees, officers or directors, and to the extent the  
24 Interrogatory seeks information about communications by any persons not made in  
25 the course of their employment by or affiliation with Amylin.

26 Amylin further objects to the Request as irrelevant and not reasonably  
27 calculated to lead to the discovery of admissible evidence as the relevance or  
28 competence of evidence on general causation is not dependent on the persons or

1 entities to which it was communicated. To the extent this Request seeks evidence  
2 that is relevant to general causation, it is duplicative of Plaintiffs' other requests  
3 that seek such evidence more directly.

4 Amylin further objects to the Request as vague and ambiguous, including but  
5 not limited to its term "any of the work they have done or authored regarding  
6 incretin medications." Amylin further objects to the Interrogatory as overbroad and  
7 unduly burdensome to the extent that it seeks information about drugs other than  
8 Byetta® or exenatide in litigation that, as it applies to Amylin, concerns only claims  
9 related to Byetta®. Amylin further objects to the Request as irrelevant and not  
10 reasonably calculated to lead to the discovery of admissible evidence insofar as  
11 it seeks communications about "incretin medications" on topics other than the  
12 general causation question at issue in this litigation. The Court's March 25, 2014  
13 order provides that "permitted discovery includes *actual scientific evidence* . . .  
14 with regard to the causal link in dispute in this case." 3/25/2014 Order at 2:20-23  
15 (emphasis added).

16 Subject to and without waiving the foregoing objections, Amylin responds as  
17 follows: Amylin refers Plaintiffs to the custodial files produced to Plaintiffs on  
18 December 21, 2012, March 8, 2013, and October 4, 2013, and to the custodial files  
19 to be included in Amylin's forthcoming productions as negotiated with Plaintiffs.  
20 Following a reasonable search, Amylin will produce nonprivileged documents  
21 found in the custodial files that are responsive to this Request. All such searches  
22 and subsequent productions will be governed by the Federal Rules of Civil  
23 Procedure, applicable orders in this case, and any agreements between Amylin and  
24 Plaintiffs. Attached as Exhibit D is a spreadsheet listing the custodians whose files  
25 have previously been produced, the custodians' job titles, and the Bates numbers  
26 containing each custodian's files. Plaintiffs can locate and identify documents  
27 responsive to this Interrogatory within these productions as readily as Amylin can.

28 **REQUEST NO. 64:**



1 To the extent not already produced in response to the preceding requests, all  
2 emails, letters, reports, memoranda and other written communications with authors,  
3 medical journals, scientific journals, any other publications, any diabetes research  
4 or research-funding organizations or persons affiliated with them, any scientific  
5 advisors, or any consultants about whether BYETTA or any other GLP-1 agonist or  
6 DPP-4 inhibitor CAUSES and/or is capable of CAUSING pancreatitis and/or  
7 pancreatic cancer.

8 **RESPONSE TO REQUEST NO. 64:**

9 Subject to the Preliminary Statement, Amylin objects to this Request as  
10 overbroad, oppressive and unduly burdensome, and as seeking information outside  
11 Amylin's custody and control as it seeks "all emails, letters, reports, memoranda  
12 and other written communications" regardless of who wrote or communicated  
13 them. Amylin further objects to the Request as irrelevant and not reasonably  
14 calculated to lead to the discovery of admissible evidence to the extent it seeks  
15 information other than scientific data. The Court's March 25, 2014 order provides  
16 that "permitted discovery includes *actual scientific evidence* . . . with regard to the  
17 causal link in dispute in this case." 3/25/2014 Order at 2:20-23 (emphasis added).  
18 To the extent this Request seeks evidence that is relevant to general causation, it is  
19 duplicative of Plaintiffs' other requests that seek such evidence more directly.

20 Amylin further objects to the Request as vague and ambiguous, including but  
21 not limited to its term "research-funding organizations or persons affiliated with  
22 them." Amylin further objects to the Interrogatory as irrelevant and not reasonably  
23 calculated to lead to the discovery of admissible evidence to the extent that it seeks  
24 information about drugs other than Byetta® or exenatide in litigation that, as it  
25 applies to Amylin, concerns only claims related to Byetta®.

26 Subject to and without waiving the foregoing objections, Amylin responds as  
27 follows: Amylin refers Plaintiffs to the custodial files produced to Plaintiffs on  
28 December 21, 2012, March 8, 2013, and October 4, 2013, and to the custodial files

1 to be included in Amylin's forthcoming productions as negotiated with Plaintiffs.  
2 Following a reasonable search, Amylin will produce nonprivileged documents  
3 found in the custodial files that are responsive to this Request. All such searches  
4 and subsequent productions will be governed by the Federal Rules of Civil  
5 Procedure, applicable orders in this case, and any agreements between Amylin and  
6 Plaintiffs. Attached as Exhibit D\_\_ is a spreadsheet listing the custodians whose  
7 files have previously been produced, the custodians' job titles, and the Bates  
8 numbers containing each custodian's files. Plaintiffs can locate and identify  
9 documents responsive to this Interrogatory within these productions as readily as  
10 Amylin can.

11 **REQUEST NO. 65:**

12 All DOCUMENTS that constitute or discuss compensation, honoraria,  
13 grants, scholarships or gifts, whether offered or actually paid, to individuals or  
14 institutions for work (including, without limitation, work done on preclinical  
15 studies, nonclinical studies, animal studies, human studies, other research, or the  
16 authorship of articles) concerning whether BYETTA or any other GLP-1 agonist or  
17 DPP-4 inhibitor CAUSES and/or is capable of CAUSING pancreatitis and/or  
18 pancreatic cancer. Include in YOUR response, without limitation, all such  
19 DOCUMENTS pertaining to Dr. Susan Bonner-Weir, Dr. David D. Dore, Dr.  
20 Daniel J. Drucker, Dr. Rajesh Garg, Dr. Fred Gorlick, Dr. Steven Kahn, Dr.  
21 Jacqueline Koehler, Dr. Robert Ratner, Dr. Jay S. Skyler, and/or the companies  
22 and/or organizations that employ them.

23 **RESPONSE TO REQUEST NO. 65:**

24 Subject to the Preliminary Statement, Amylin objects to this Request as  
25 irrelevant and not reasonably calculated to the lead to the discovery of admissible  
26 evidence as it seeks information other than scientific data. The Court's March 25,  
27 2014 order provides that "permitted discovery includes *actual scientific evidence* . .  
28 . with regard to the causal link in dispute in this case." 3/25/2014 Order at 2:20-23

1 (emphasis added). The financial information sought by this Request has no  
2 tendency to prove whether Byetta® causes pancreatic cancer.

3 Amylin further objects to the Request as vague and ambiguous, including but  
4 not limited to its term “research-funding organizations or persons affiliated with  
5 them.” Amylin further objects to the Interrogatory as overbroad and unduly  
6 burdensome to the extent that it seeks information about drugs other than Byetta®  
7 or exenatide in litigation that, as it applies to Amylin, concerns only claims related  
8 to Byetta®.

9 **REQUEST NO. 66:**

10 All of YOUR DOCUMENT retention, destruction and archiving policies that  
11 apply to BYETTA preclinical, nonclinical, animal, human and/or observational  
12 studies; other studies addressing, in whole or in part, whether BYETTA CAUSES  
13 and/or is capable of CAUSING pancreatitis and/or pancreatic cancer; BYETTA  
14 ADVERSE EVENTS; and any other DOCUMENTS addressing whether BYETTA  
15 CAUSES and/or is capable of CAUSING pancreatitis and/or pancreatic cancer.

16 **RESPONSE TO REQUEST NO. 66:**

17 Subject to the Preliminary Statement, Amylin objects to this Request as not  
18 reasonably calculated to lead to admissible evidence as “retention, destruction and  
19 archiving policies” are not scientific evidence relevant to general causation. The  
20 Court’s March 25, 2014 order provides that “permitted discovery includes *actual*  
21 *scientific evidence* . . . with regard to the causal link in dispute in this case.”  
22 3/25/2014 Order (Doc. No. 377) at 2:20-23 (emphasis added).

23 Amylin further objects to this Request to the extent it seeks documents and  
24 information protected by the attorney-client privilege and/or attorney work product  
25 doctrine.

26 Amylin further objects to this Request as overbroad and vague, including  
27 without limitation its terms “retention, destruction and archiving policies,” “studies  
28 addressing, in whole or in part, whether BYETTA CAUSES and/or is capable of

1 CAUSING pancreatitis and/or pancreatic cancer,” and “is capable of CAUSING.”  
2 Amylin further objects to the Request as overbroad, unduly burdensome and  
3 oppressive to the extent it seeks documents that are not reasonably accessible.

4 Subject to and without waiving the foregoing objections, Amylin responds as  
5 follows: Amylin refers Plaintiffs to documents in its prior productions, including  
6 but not limited to documents at Bates numbers AMYLN0001959059-  
7 AMYLN0001959064. Amylin objects to undertaking any further effort to locate or  
8 produce documents responsive to this request, especially during the general  
9 causation phase of discovery.

10 **REQUEST NO. 67:**

11 To the extent that YOU have withheld any DOCUMENTS responsive to any  
12 of these requests under any claim of privilege, produce a privilege log as required  
13 by Fed. R. Civ. P. 26.

14 **RESPONSE TO REQUEST NO. 67:**

15 To the extent Amylin withholds documents under any claim of privilege, it  
16 will produce a privilege log as required by Federal Rule of Civil Procedure 26.

17  
18  
19 Dated: May 9, 2014

O'MELVENY & MYERS LLP  
RICHARD B. GOETZ  
AMY J. LAURENDEAU

21 By: /s/ Amy J. Laurendeau  
22 Amy J. Laurendeau  
23 Attorneys for Defendant  
24 Amylin Pharmaceuticals, LLC  
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- **Defendant Amylin Pharmaceuticals, LLC's Responses and Objections to Plaintiffs' General Causation Requests for the Production of Documents;**
- **Exhibits A-D to Defendant Amylin Pharmaceuticals, LLC's Responses and Objections to Plaintiffs' General Causation Requests for the Production of Documents**

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/s/Amy J. Laurendeau  
Amy J. Laurendeau